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Windheuser et al.

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(54) **GUIDEWIRE AND CATHETER LOCKING DEVICE AND METHOD**

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(73) Assignee: **Boston Scientific Corporation**, Natick, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/512,997**

(22) Filed: **Feb. 25, 2000**

Related U.S. Application Data

(63) Continuation of application No. 09/080,520, filed on May 18, 1998, now Pat. No. 6,096,009, which is a continuation-in-part of application No. 08/926,200, filed on Sep. 9, 1997, now Pat. No. 6,007,522
(60) Provisional application No. 60/025,235, filed on Sep. 13, 1996.

(51) **Int. Cl.**[7] **A44B 1/04**; A61M 5/178
(52) **U.S. Cl.** **604/165.02**; 604/538
(58) **Field of Search** 604/53, 103, 117, 604/159, 165, 208, 220, 283, 165.01, 165.02, 165.04, 532, 534, 538; 24/333, 543, 339, 340, 346, 540, 562; 600/101, 104, 106, 112, 131, 139, 147, 148, 585

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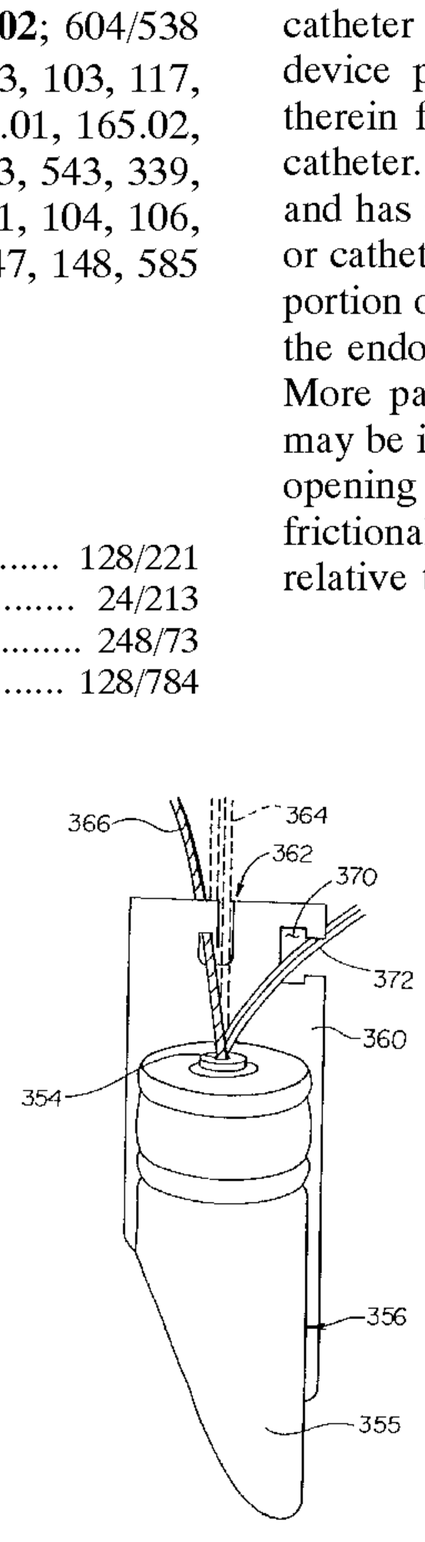
(74) *Attorney, Agent, or Firm*—Crompton, Seager & Tufte, LLC

(57) **ABSTRACT**

Locking device that is mounted on an endoscope or the like for selectively securing the position of a guide wire and/or catheter relative to the endoscope or the like. The locking device preferably includes a side wall with an opening therein for receiving the proximal end of a guide wire or catheter. The opening is preferably J-shaped or boot shaped, and has an entry end and a locking end. Once a guide wire or catheter is in a desired position within a body cavity, the portion of the guide wire or catheter that extends outside of the endoscope or the like may be moved into the opening. More particularly, a portion of the guide wire or catheter may be inserted by an operator through the entry end of the opening and into the locking end, wherein the locking end frictionally secures the position of the guide wire or catheter relative to the endoscope or the like.

8 Claims, 15 Drawing Sheets



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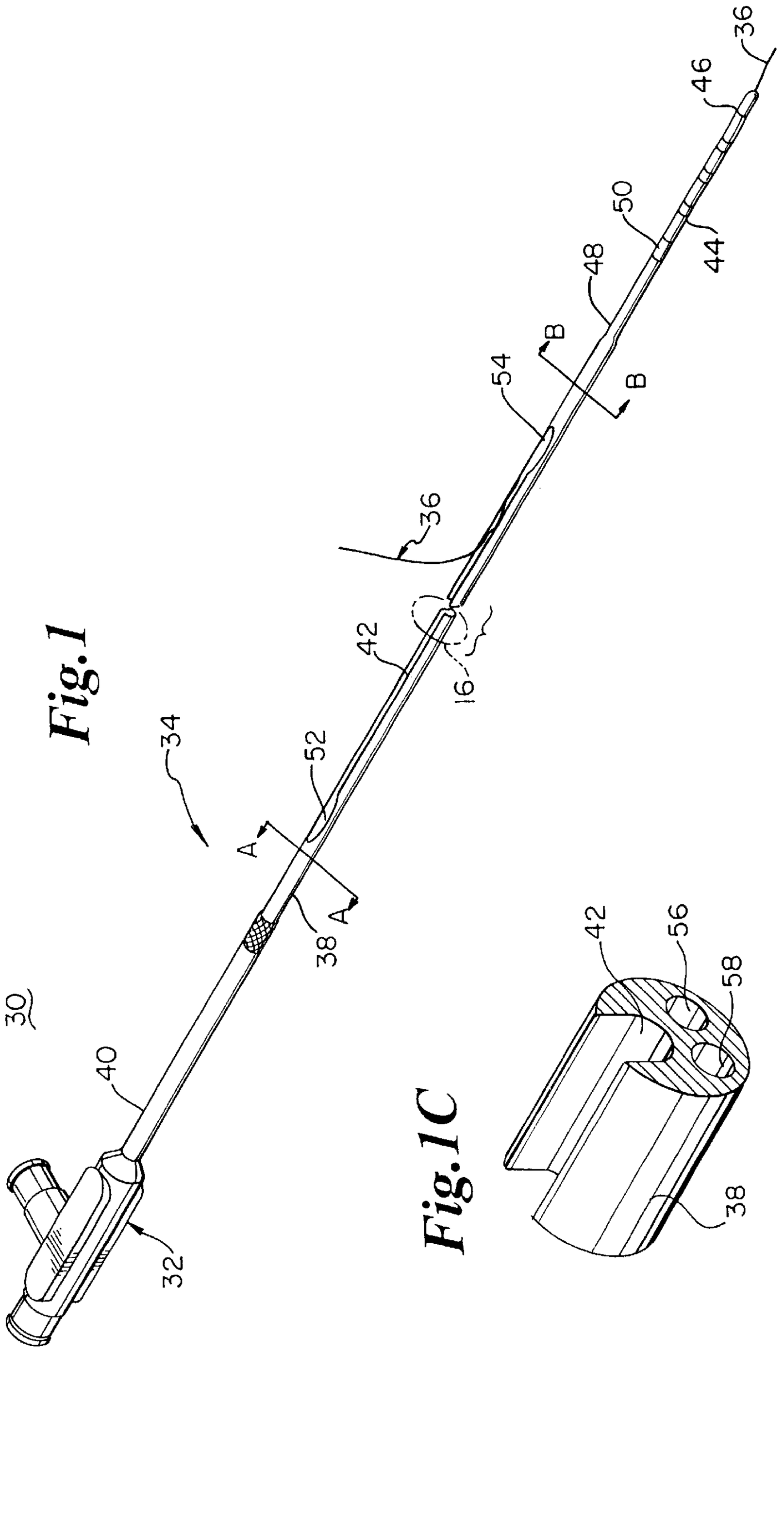


Fig. 1

Fig. 1C

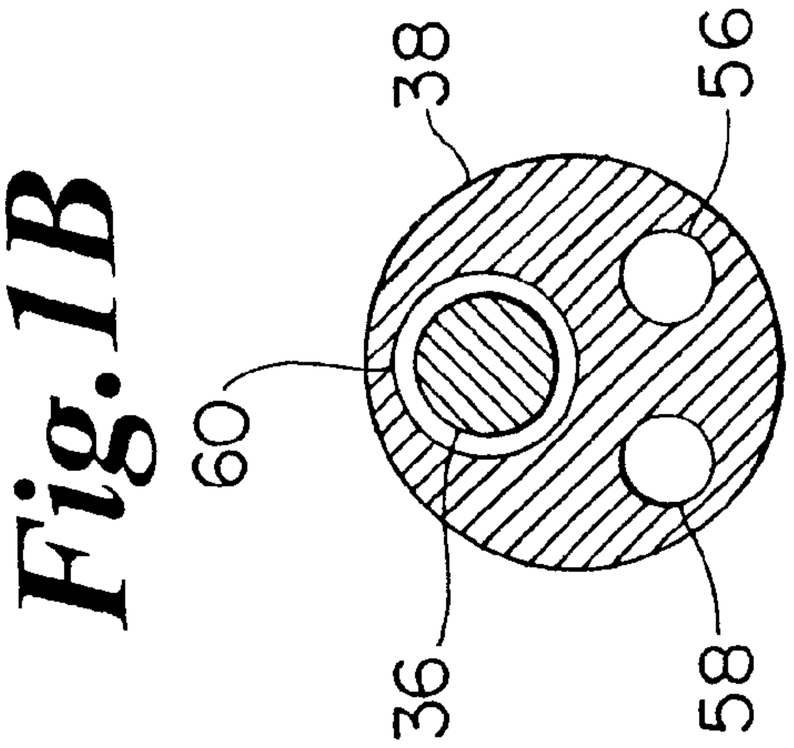


Fig. 1B

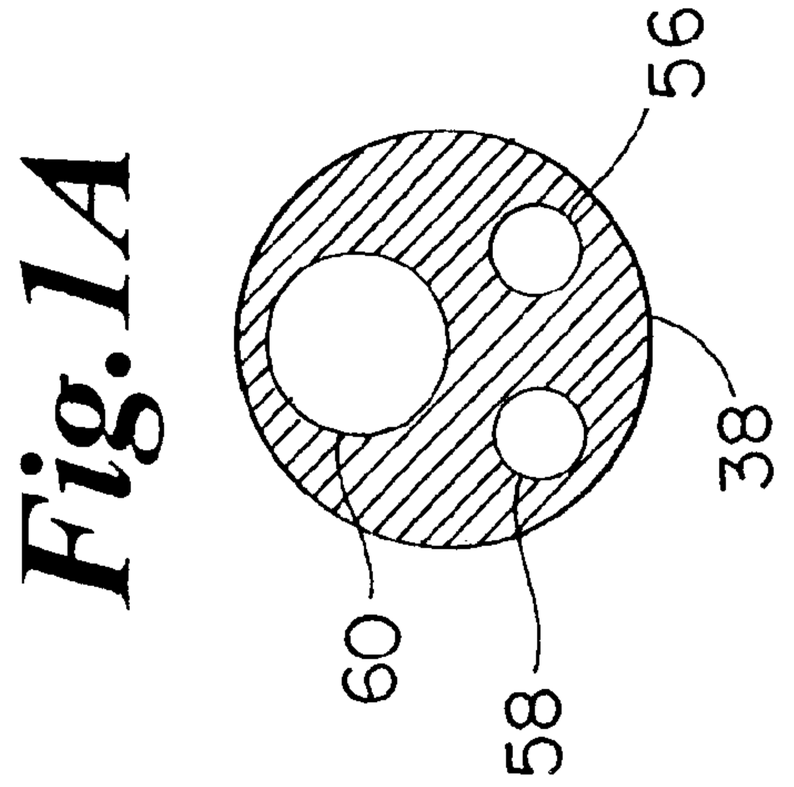
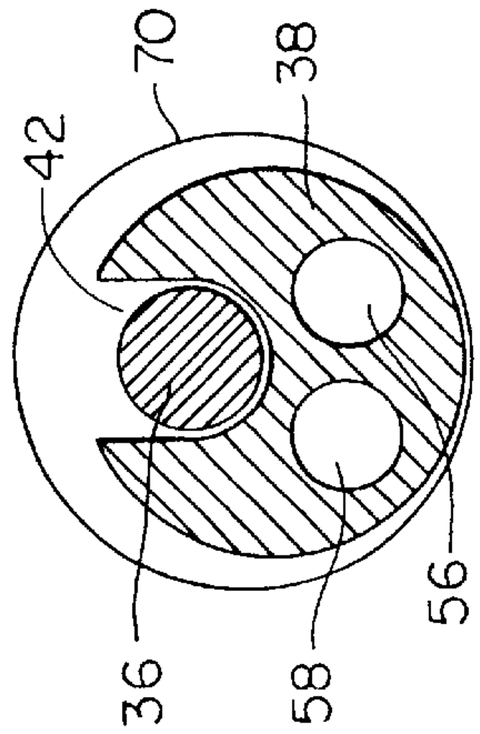


Fig. 1A

Fig. 2A



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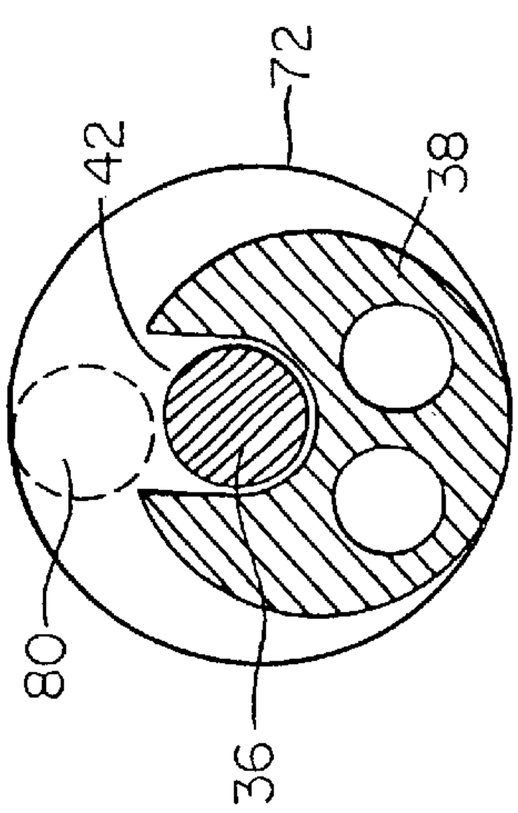


Fig. 2C

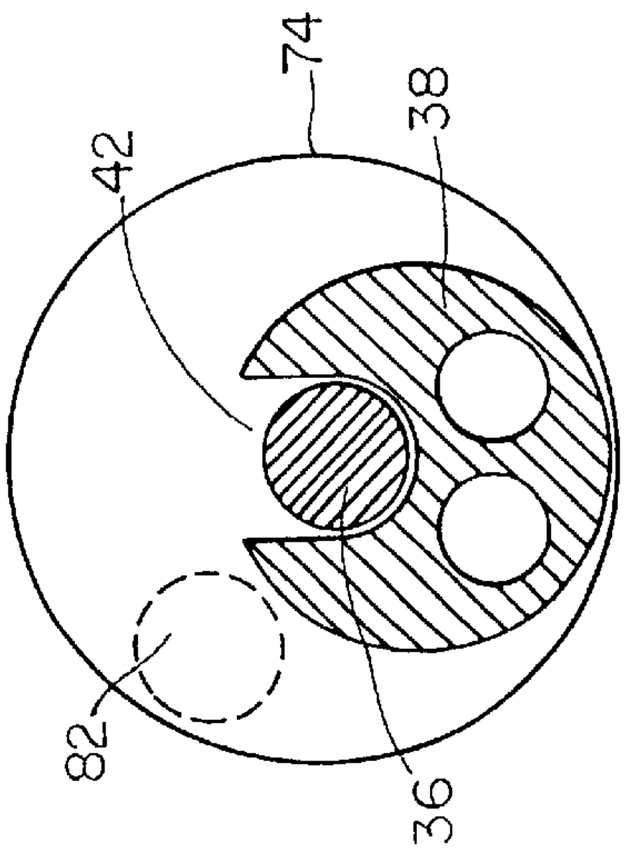
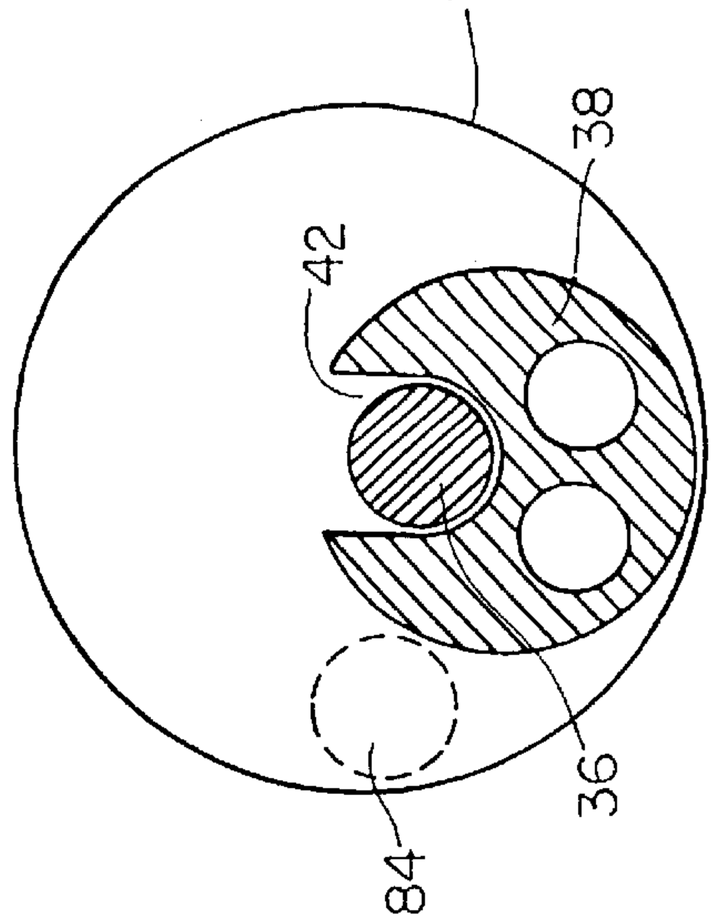


Fig. 2D



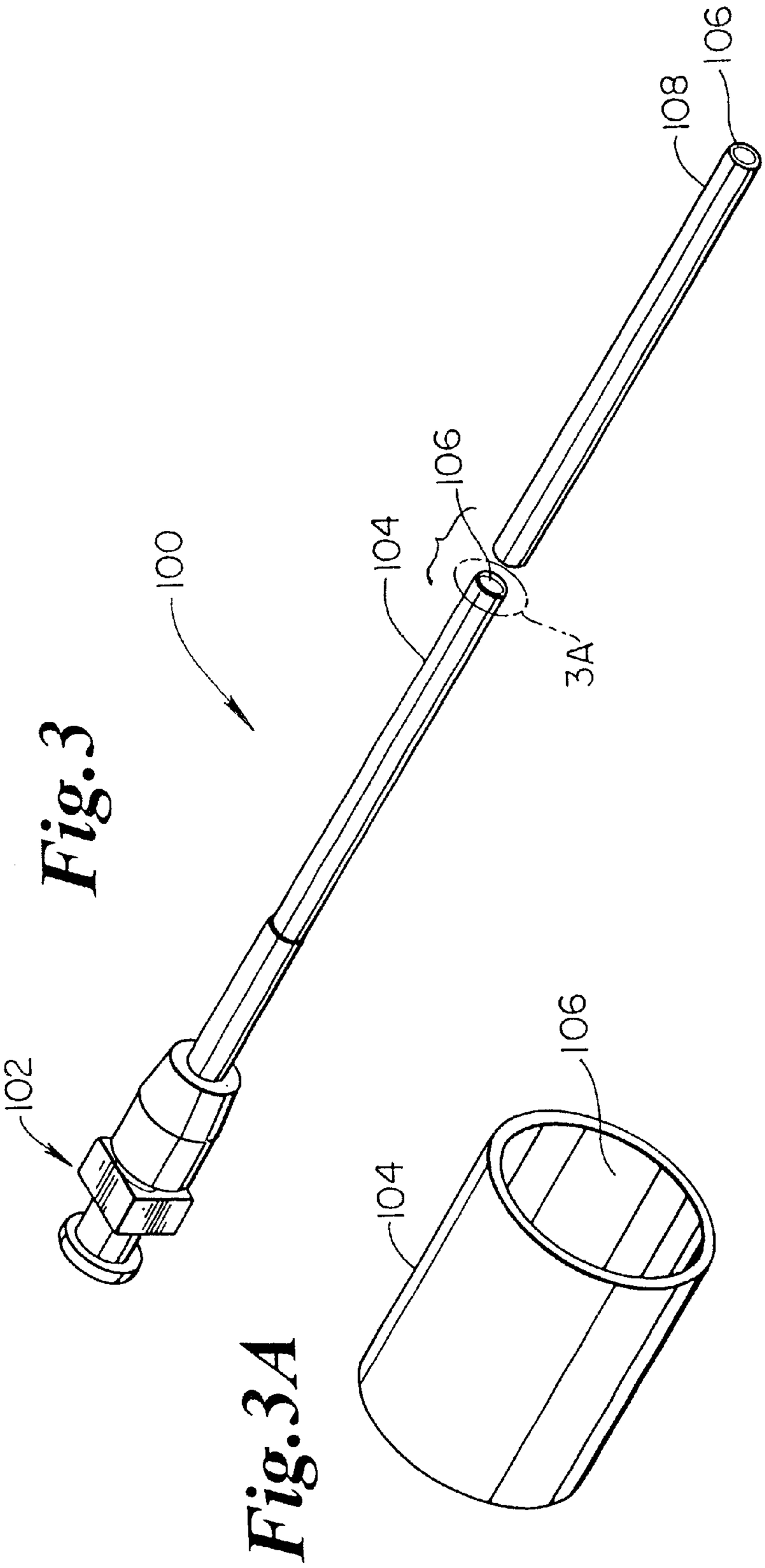


Fig. 3

Fig. 3A

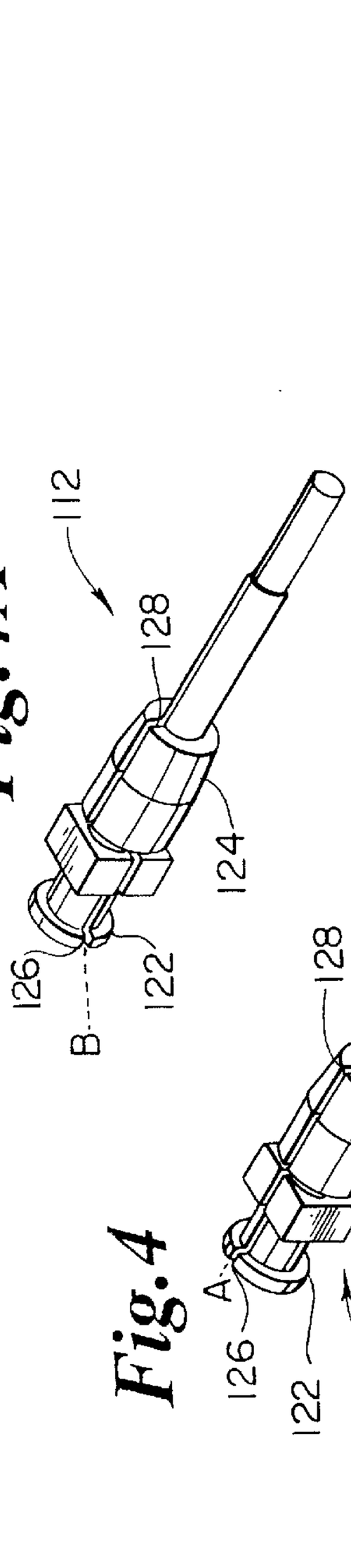


Fig. 4A

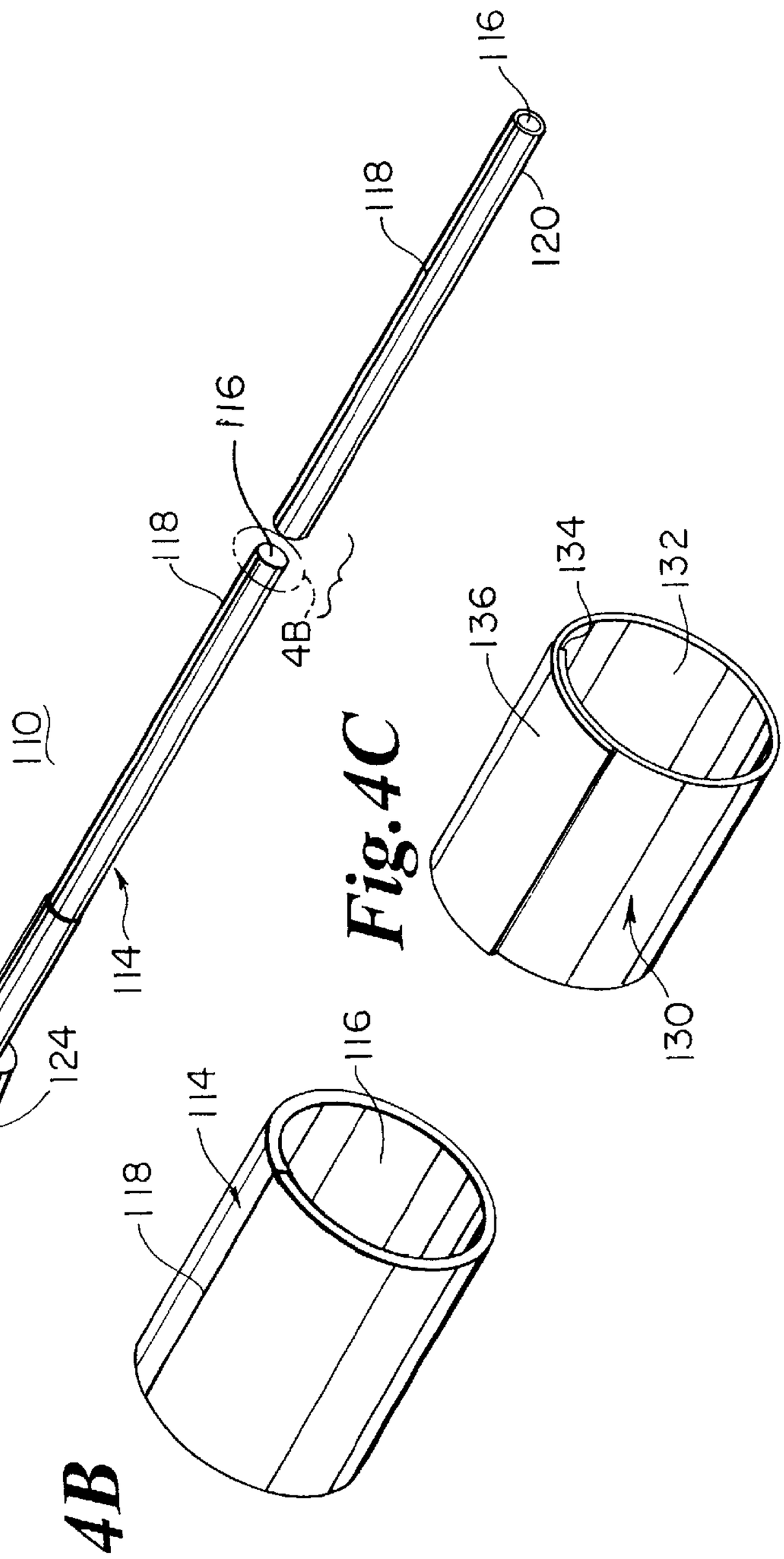


Fig. 4

Fig. 4C

Fig. 4B

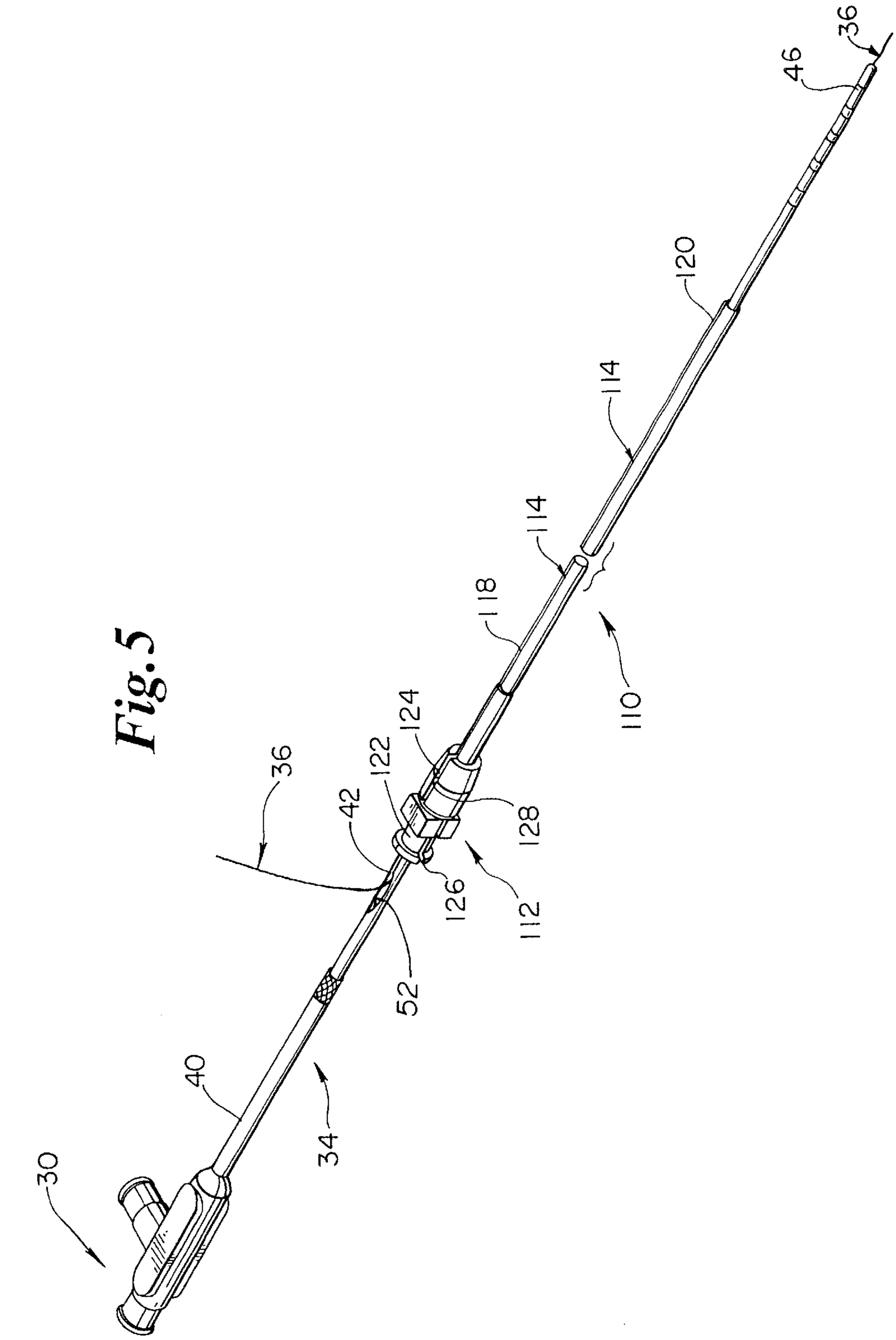
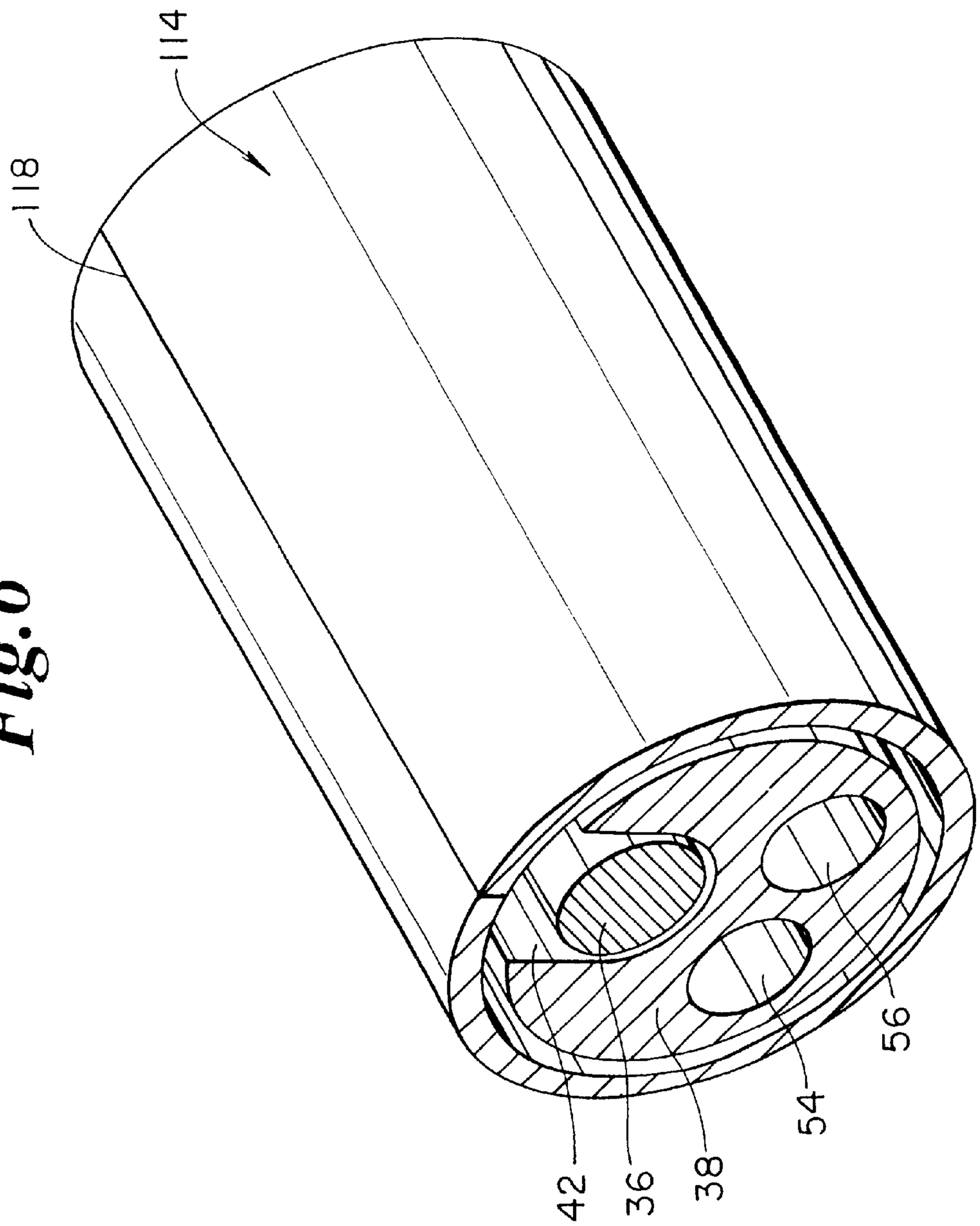


Fig. 5



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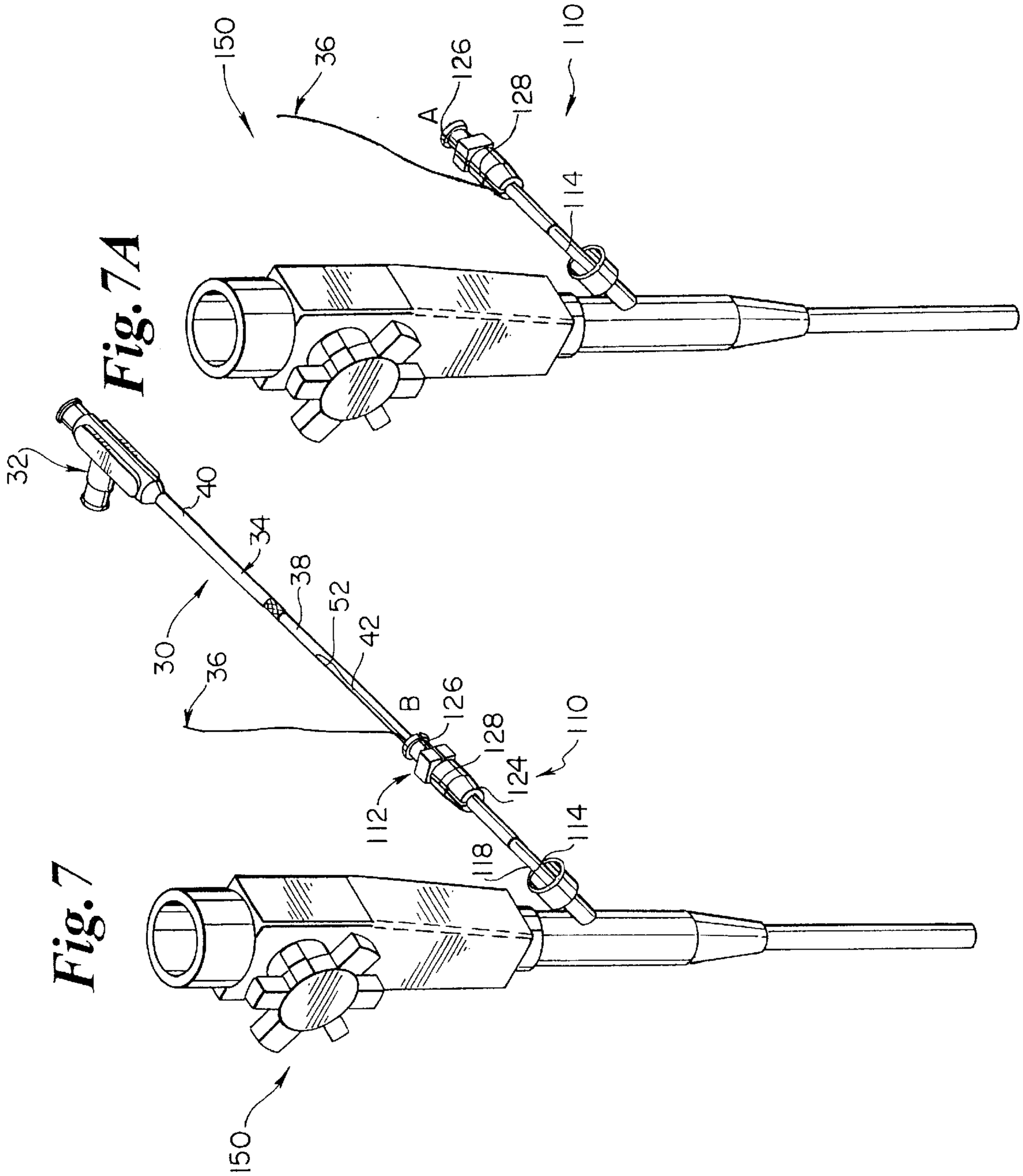
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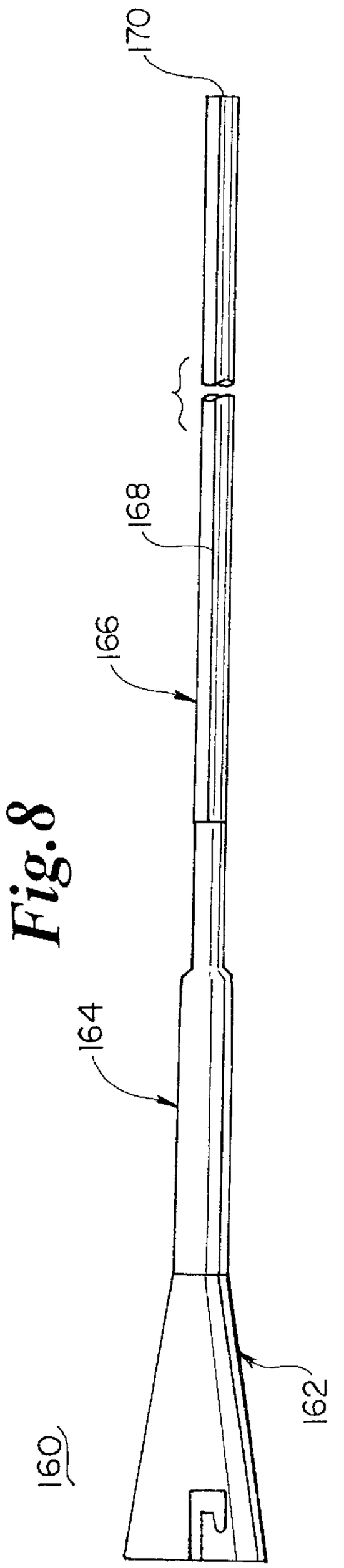
Fig. 7

Fig. 7A



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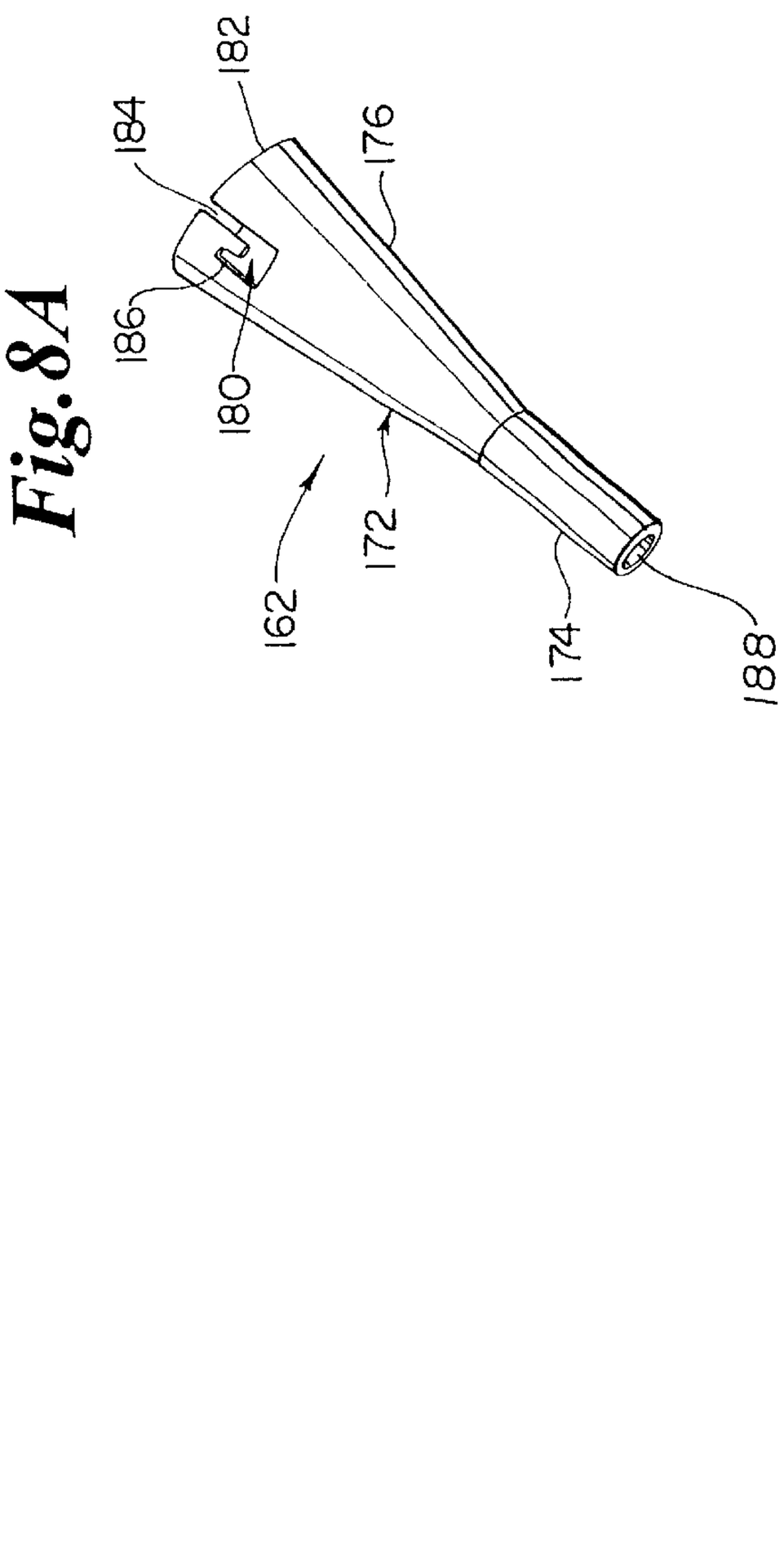


Fig. 8A

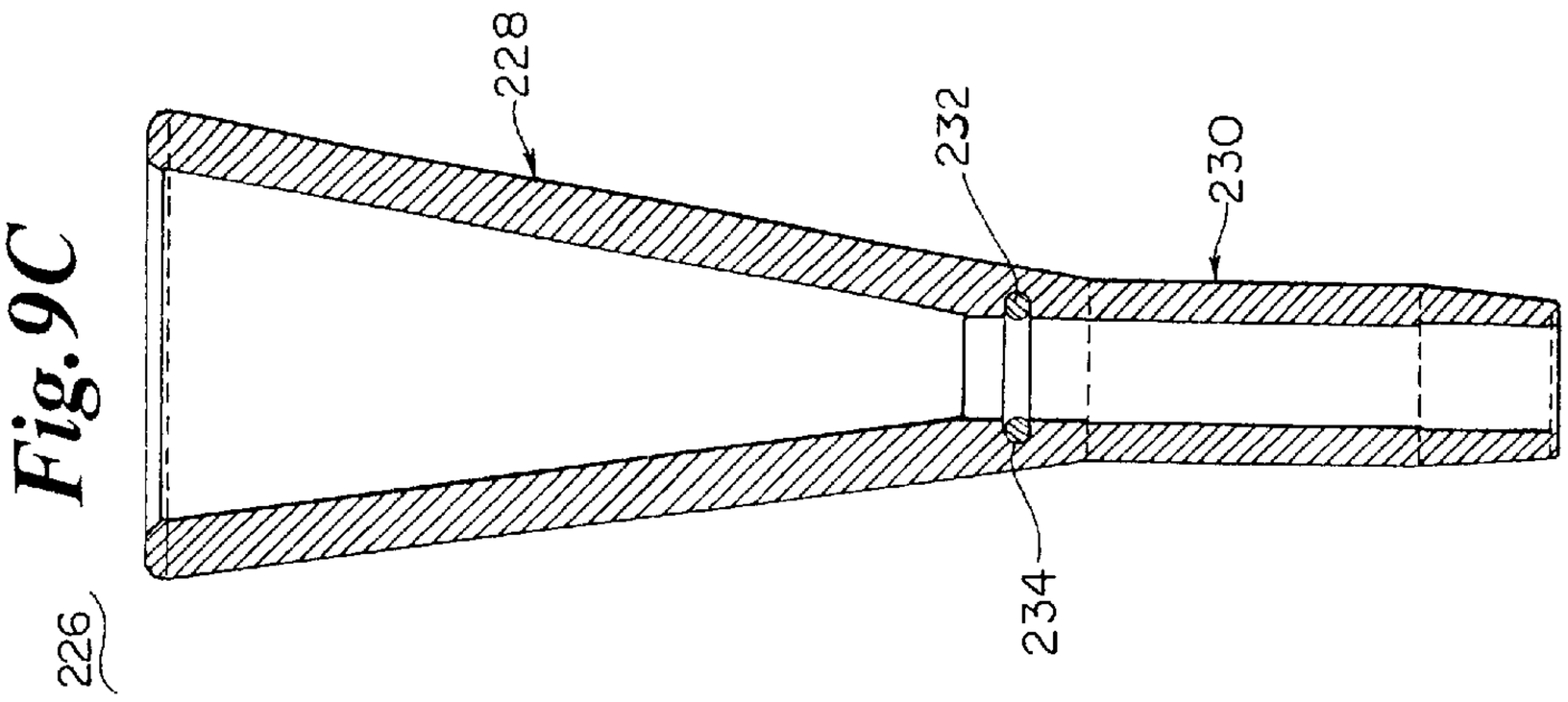


Fig. 9C

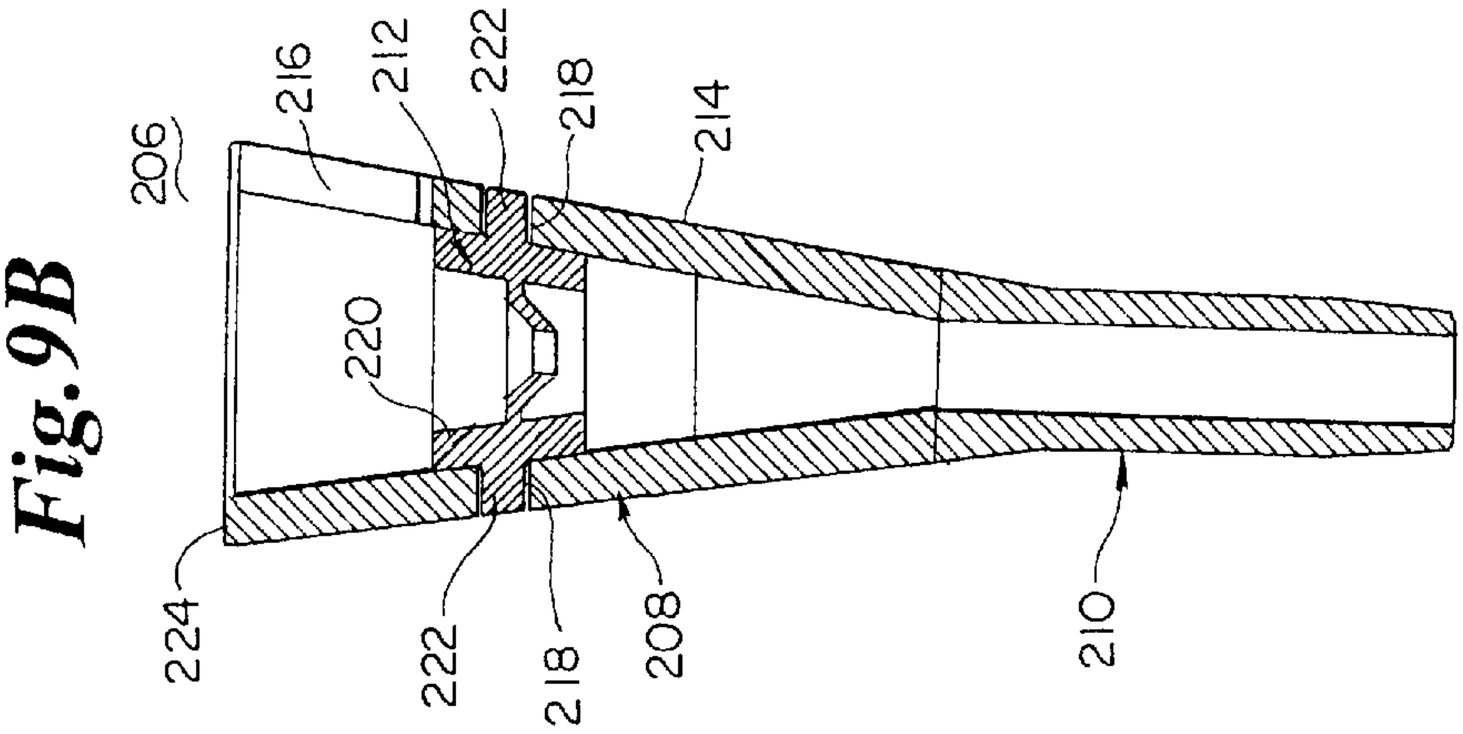


Fig. 9B

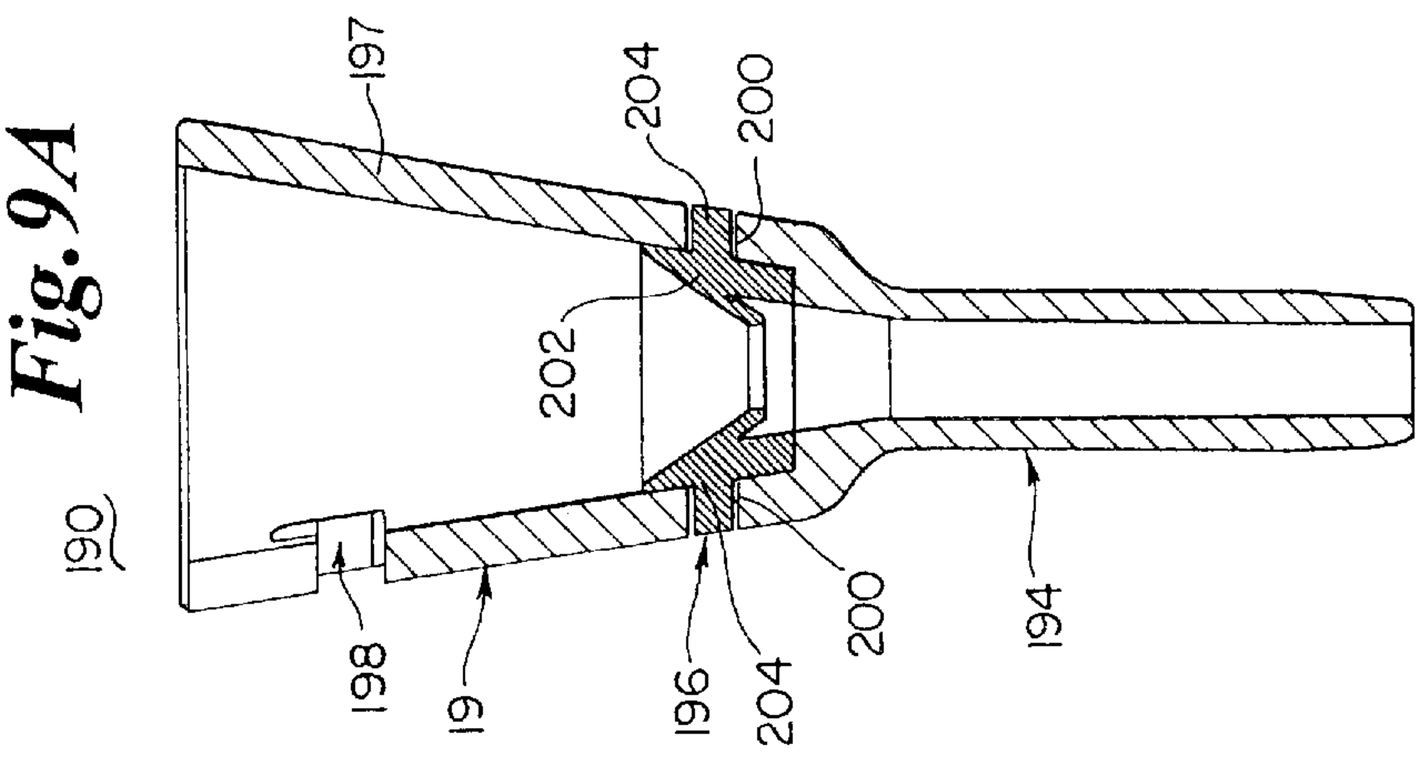


Fig. 9A

Fig. 9F

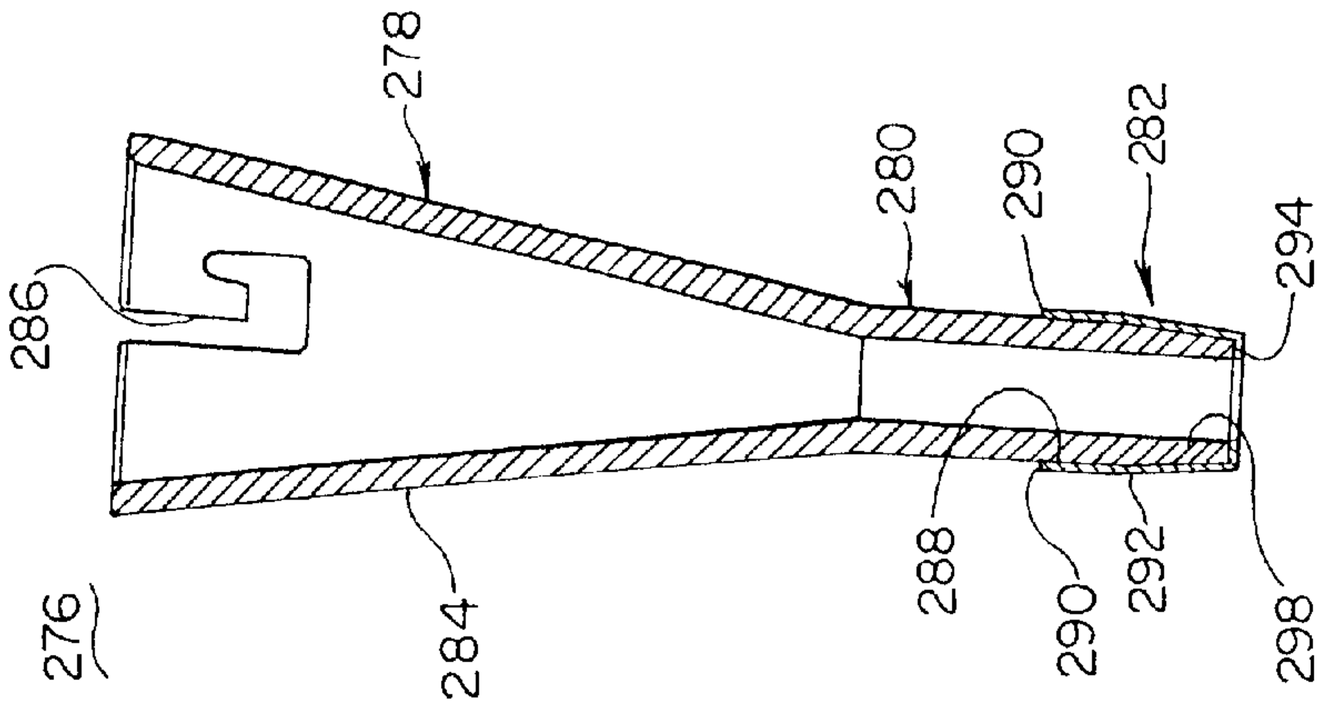


Fig. 9E

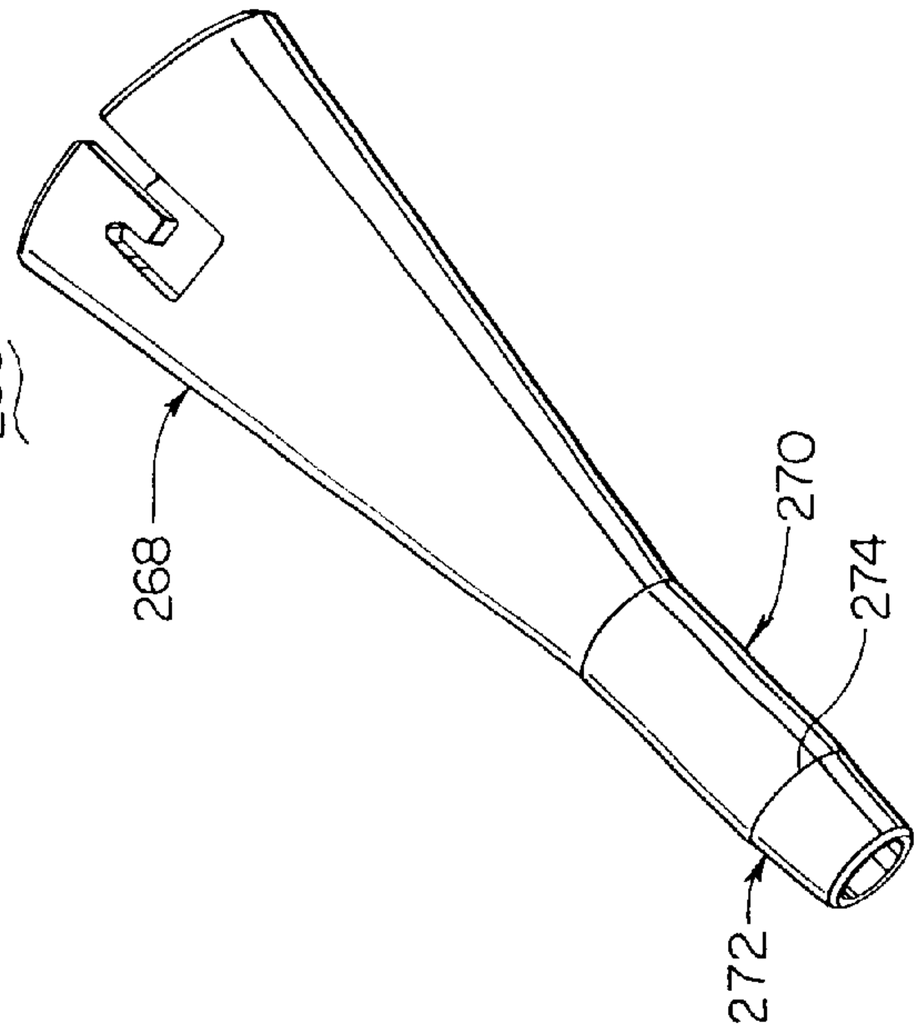
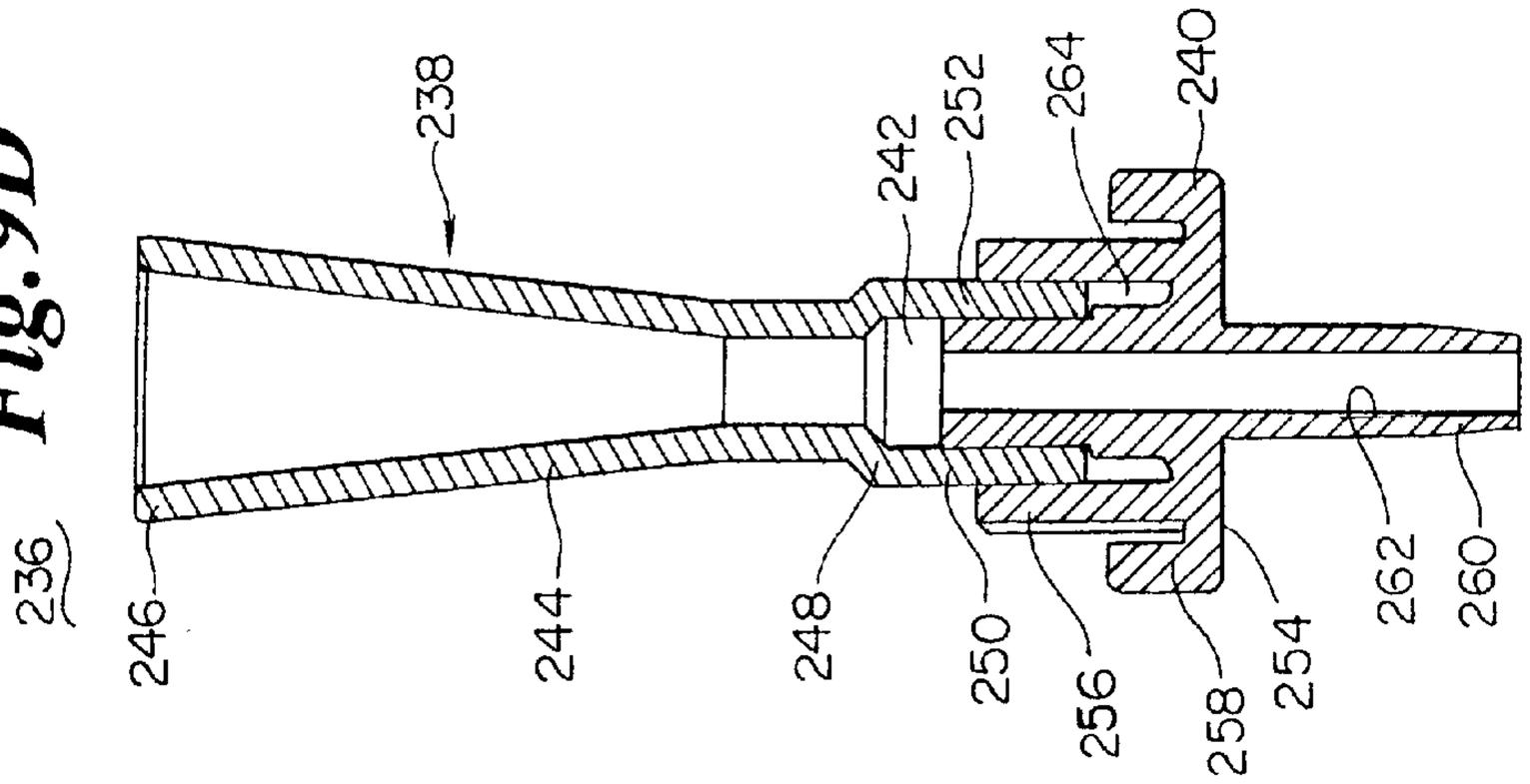


Fig. 9D



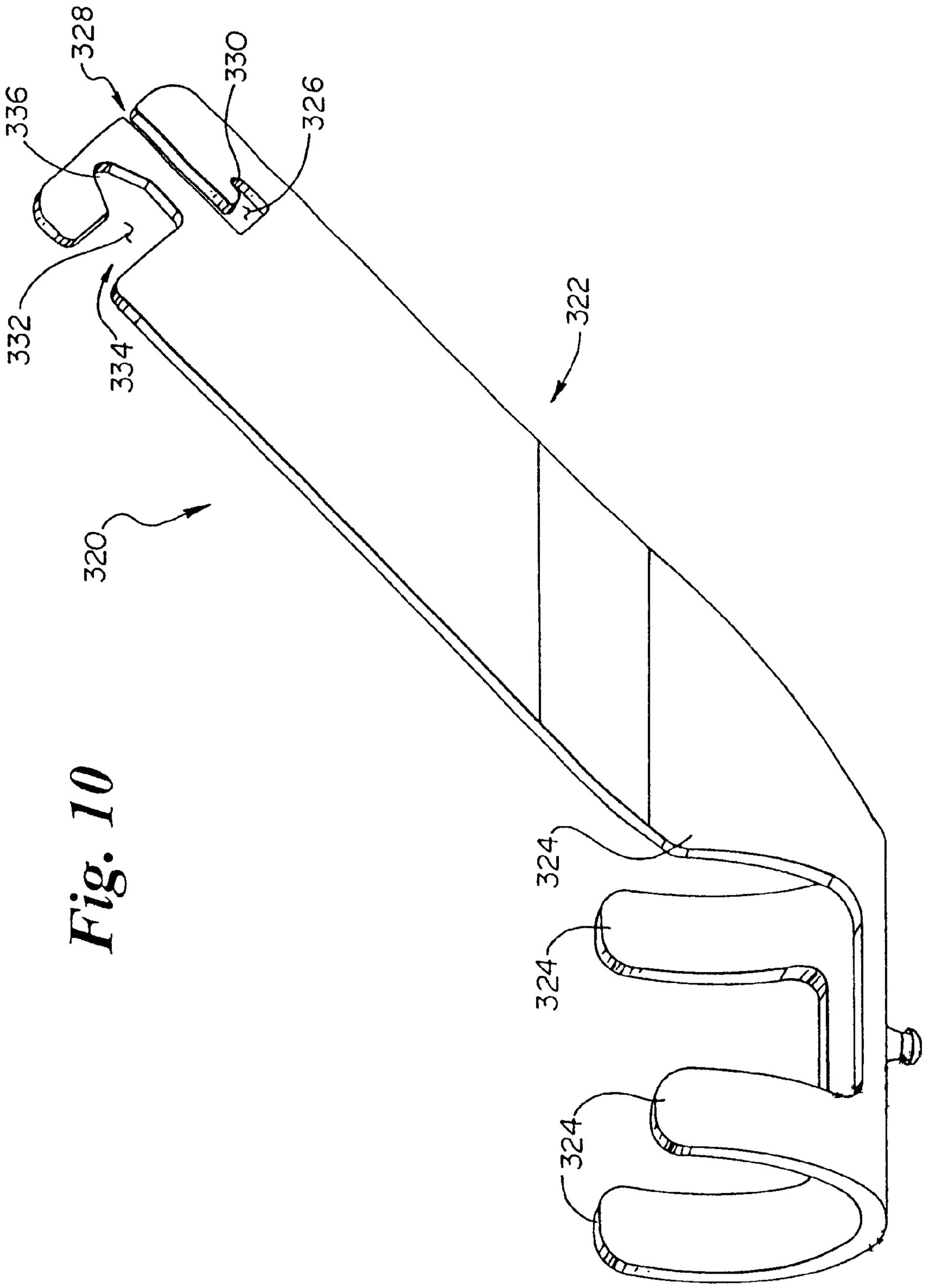


Fig. 10

Fig. 11

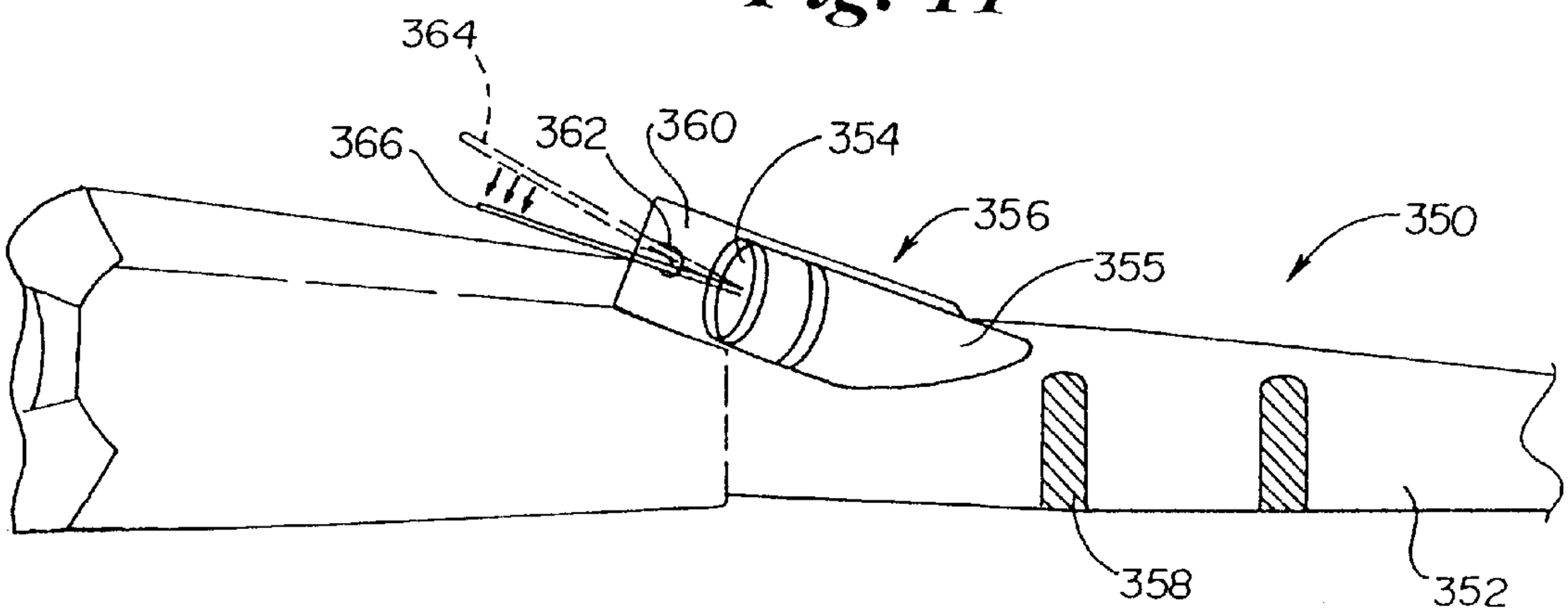

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Fig. 12

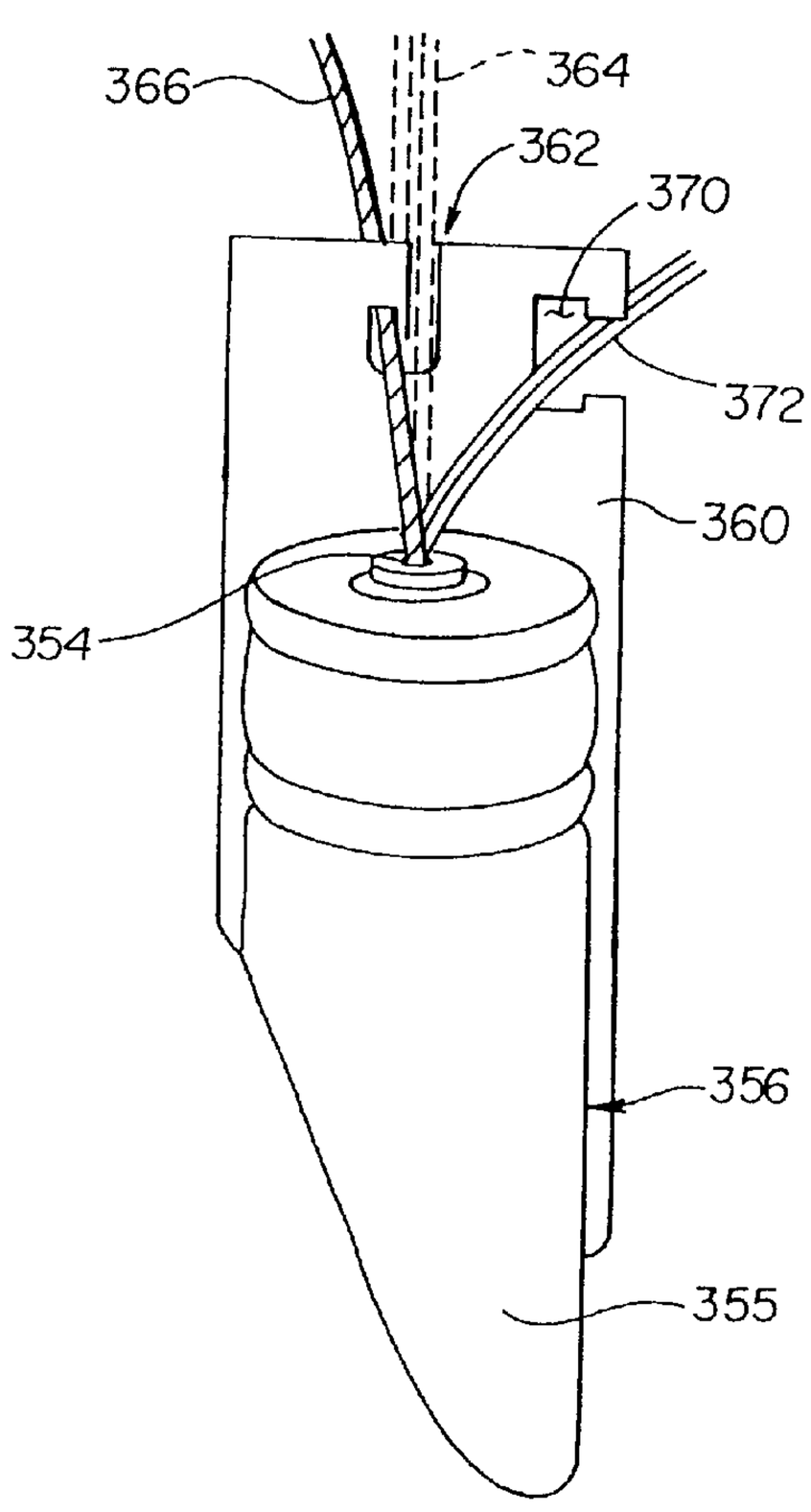
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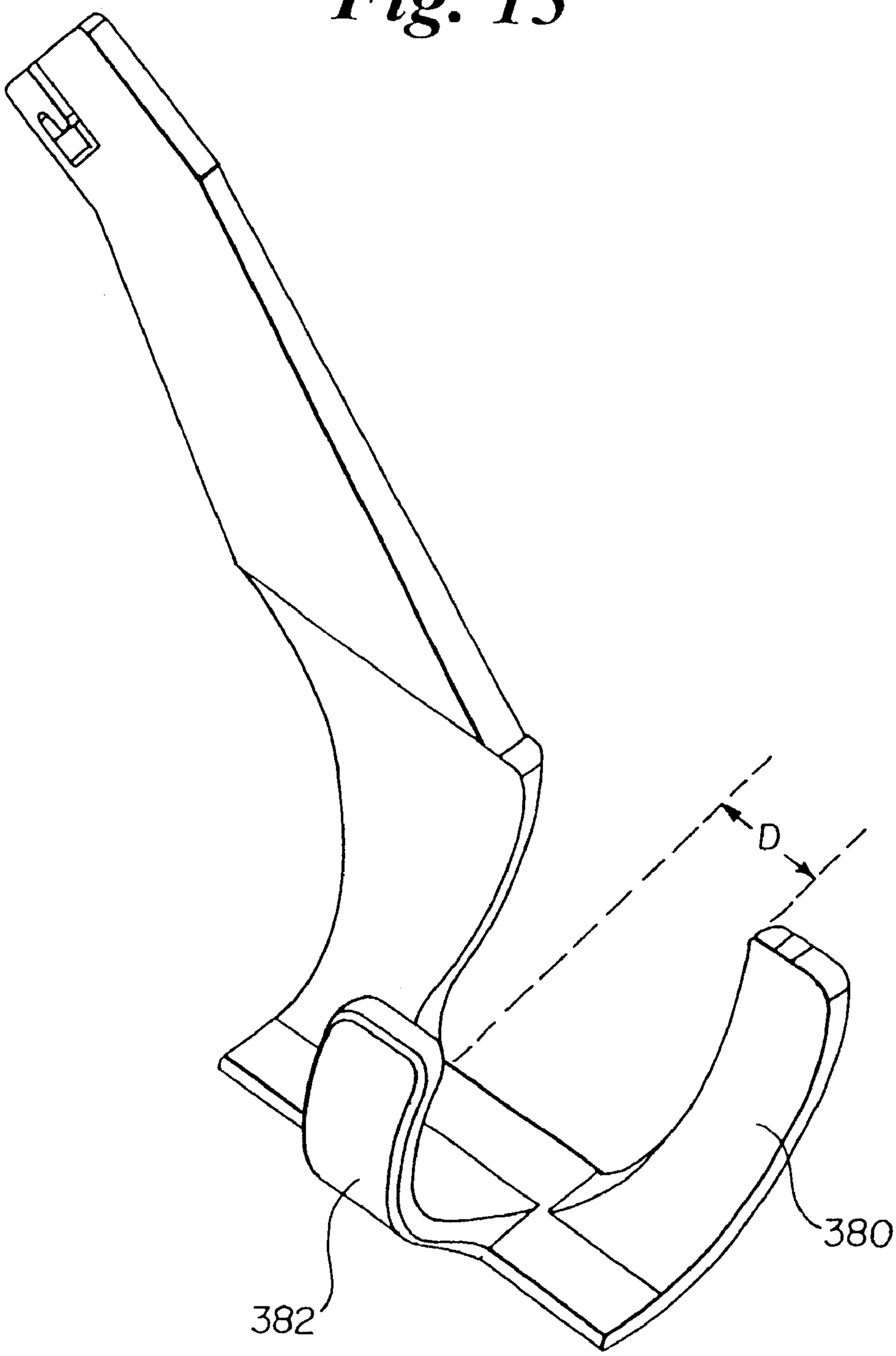
Fig. 13



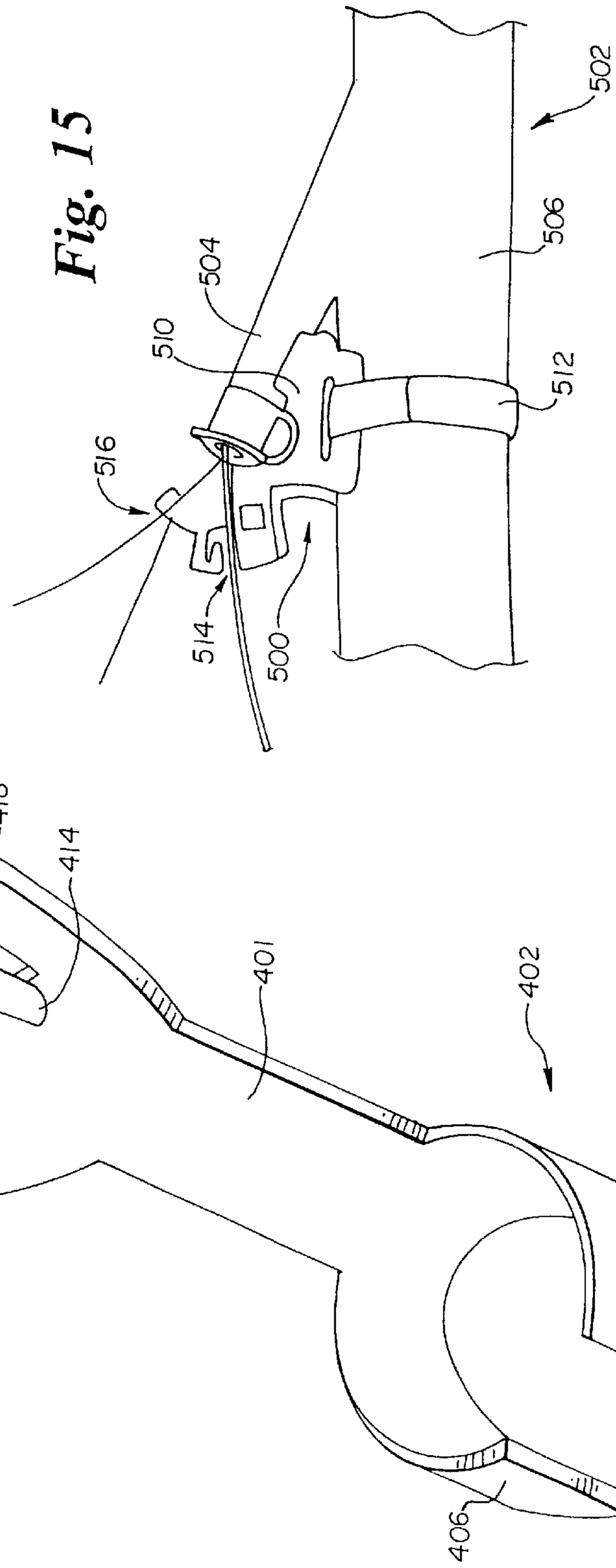

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Fig. 15

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Fig. 14

GUIDEWIRE AND CATHETER LOCKING DEVICE AND METHOD

This application is a continuation of U.S. patent application Ser. No. 09/080,520, filed May 18, 1998, now U.S. Pat. No. 6,096,009, issued Aug. 1, 2000 which is a continuation-in-part application of U.S. patent application Ser. No. 08/926,200, filed on Sep. 9, 1997, entitled "Single Operator Exchange Biliary Catheter", now U.S. Pat. No. 6,007 522, issued Dec. 28, 1999, which claims priority under 35 U.S.C. §119(e) to provisional application U.S. Ser. No. 60/025,235, filed Sep. 13, 1996, entitled "Single Operator Exchange Biliary Catheter".

FIELD OF THE INVENTION

The present invention relates to a guide wire and/or a catheter locking device for use in catheter procedures within the human anatomy, and methods of using the same. The locking device is particularly useful during catheter exchange procedures. The present invention includes a locking device that is attached to an endoscope, a guide catheter, or other guiding type catheter that receives a guide wire and/or another catheter. The locking device is used to selectively secure the guide wire and/or catheter in a desired position within the endoscope or guiding type catheter. This may reduce the likelihood that the guide wire and/or catheter will move from a desired placement during a procedure, such as a catheter exchange procedure.

DESCRIPTION OF THE PRIOR ART

Endoscopic procedures for treating abnormal pathologies within the alimentary canal system and biliary tree (including the biliary, hepatic, and pancreatic ducts) are increasing in number. The endoscope provides access to the general area of a desired duct using direct visualization. However, the duct itself must be navigated using a catheter in conjunction with fluoroscopy and guide wires. Catheters are known for treatment of targeted anatomical regions. Known methods and devices for using biliary catheters for accessing the biliary tree for performing catheter procedures are disclosed in Weaver et al., U.S. Pat. No. 5,397,302 and Karpiel, U.S. Pat. No. 5,320,602, the disclosures of which are herein incorporated by reference. In general, for treatment of an abnormal pathology within a patient's biliary tree, an endoscope is first introduced into the mouth of the patient. The endoscope includes a proximal end and a distal end, and has a lumen extending longitudinally between the proximal and distal ends. The endoscope is guided through the patient's alimentary tract or canal until an opening at the distal end of the endoscope is proximate the area to receive treatment. At this point, the endoscope allows other components, such as a catheter, to access the targeted area. For visualization or treatment within the biliary tree, the distal end of the endoscope is positioned proximate the papilla of vater leading to the common bile duct and the pancreatic duct. A catheter is guided through the lumen of the endoscope until a distal tip of the catheter emerges from the opening at the distal end of the endoscope.

The catheter may be used for accessing the biliary tree. The distal end of the catheter is guided through the orifice to the papilla of vater (located between the sphincter of oddi) leading to the common bile duct and the pancreatic duct. A guide wire may be used in conjunction with the catheter to facilitate accessing a desired location within the biliary tree. The guide wire is inserted in an opening at a proximal end of the catheter and guided through the catheter until it emerges from the distal end of the catheter.

If visualization of the common bile duct is desired, the guide wire is guided into the common bile duct. The catheter is advanced over the guide wire, as previously described, until the distal end of the catheter is positioned in the common bile duct at the desired location. The catheter is now in position for delivery of contrast media for fluoroscopic visualization of anatomical detail within the common bile duct. Visualization may reveal selected areas within the common bile duct that require treatment. To treat the selected areas, a different catheter is typically required, necessitating a catheter exchange. A catheter exchange typically involves removing the first catheter from the endoscope over the guide wire, and advancing a second catheter over the guide wire to the desired treatment site. Thus, once the guide wire is in place relative to the targeted area, it is highly desirable to maintain the position of the guide wire during subsequent catheter procedures, including during a catheter exchange procedure. If the guide wire moves during such a procedure, the guide wire may have to be re-directed through the body ducts to the target site, which is often a difficult, time consuming and tedious task.

In addition to performing a catheter exchange procedure, it may also be desirable to perform a guide wire exchange procedure. This may be desirable when, for example, a first guide wire is too large to fit through a desired body duct, or otherwise lacks the desired characteristics. Under these circumstances, a physician may leave the catheter in place, withdraw the first guide wire from the catheter, and insert a second guide wire through the catheter to the desired site. During this procedure, the catheter guides the guide wire to the desired site. Thus, once the catheter is positioned at a target site, it is highly desirable to maintain the position of the catheter during a guide wire exchange procedure so that the second guide wire may be guided directly to the desired site in a minimum amount of time.

To maintain the position of a guide wire and/or catheter, a physician typically must grasp the proximal end of the guide wire and/or catheter with one hand, and performing the corresponding exchange with the other. This is difficult, and often results in the movement of the guide wire and/or catheter. Therefore, it would be desirable to provide a locking device whereby the physician can secure the position of the guide wire and/or catheter during an exchange procedure, thereby freeing both hands to perform other tasks.

SUMMARY OF THE INVENTION

The present invention overcomes many of the disadvantages of the prior art by providing a locking device that is mounted on an endoscope or the like for selectively securing the position of a guide wire and/or catheter relative to the endoscope or the like. The locking device preferably includes a side wall with an opening therein for receiving the guide wire or catheter near its proximal end or at any point along the guide wire or catheter's length depending upon how far it is inserted. The opening is preferably J-shaped or boot shaped, and has an entry slot and a locking slot. Once a guide wire or catheter is in a desired position within a body cavity, a portion of the guide wire or catheter that extends outside of the endoscope or the like is aligned with the opening and may be moved into the opening in use. More particularly, a portion of the guide wire or catheter may be inserted by an operator through the entry slot of the opening and into the locking slot, wherein the locking slot frictionally secures the position of the guide wire or catheter relative to the endoscope or the like.

In one illustrative embodiment, the locking device includes a body member that is funnel shaped including a

horn and a neck with a lumen extending therethrough. The horn has a side wall with an opening provided therein. The neck is operatively attached to the endoscope or the like proximate an access port. In this configuration, a proximal portion of the guide wire or catheter extends out of the access port of the endoscope or the like and through the lumen of the locking device. Once a guide wire or catheter is in a desired position within a body cavity, the proximal portion of the guide wire or catheter may be moved into the opening in the body member of the locking device, and frictionally fit therein.

In another illustrative embodiment, the locking device is adapted for use with an endoscope having a side port. The side port is in fluid communication with one or more lumens, and may receive a guide wire or catheter therein. In this embodiment, the locking device includes a body member, an attachment mechanism and a securing mechanism. The attachment mechanism preferably includes one or more hook members that engage the main shaft of the endoscope near the side port. These hook members tend to clip or secure the locking device to the main shaft of the endoscope. The body member extends from the hook members generally parallel to the side port. The securing mechanism, which is preferably an opening in the body member, is preferably positioned near the end of the body member and proximate the side port opening of the endoscope. Once a guide wire or catheter is in a desired position within a body cavity, the proximal portion of the guide wire or catheter, which extends outside of the side port of the endoscope, may be moved into the opening of the locking device and frictionally fit therein. In preferred embodiments, the opening includes an entry slot and a locking slot, as described above.

It is contemplated that the locking device may include more than one securing mechanism for securing more than one guide wire or catheter or combination of guide wires and catheters. This is preferably accomplished by including two or more openings in the body member of the locking device. For example, one opening may be substantially J-shaped for securing a guide wire. Another opening may be boot shaped for securing a catheter. The boot shape is similar to the J-shape but has increased dimensions for receiving the larger catheter shaft.

In use, a guide wire or catheter may be inserted into the lumen of an endoscope or the like. The locking device, which is preferably operatively attached to the shaft of the endoscope or the like, has a wall with an opening therein. The opening is preferably positioned proximate an access port of the endoscope or the like. As described above, the opening preferably has a locking slot that has a reduced dimension relative to the outside portion of the guide wire or catheter. Once the guide wire or catheter is in a desired position within a body cavity, the proximal portion of the guide wire or catheter is selectively secured to the locking device by positioning the guide wire or catheter in the locking slot of the opening.

It is contemplated that the locking device may be used in conjunction with any catheter that receives another device such as a guide wire or another catheter. For example, it is contemplated that the locking device may be used in conjunction with endoscopes, guide catheters, angioplasty catheters, etc. It is also recognized that when securing a guide wire during a catheter exchange procedure, the first and second catheters should be rapid-exchange type catheters to allow access to the guide wire proximate the access port during at least most of the catheter exchange procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further described with reference to the accompanying drawings, wherein like numbers refer to like parts in several views and wherein:

FIG. **1** is a perspective view of a catheter in accordance with the present invention having a U-shaped channel and guide wire lumen for directing a guide wire along its shaft and for facilitating rapid catheter exchange;

FIG. **1**A is a cross-sectional view of the catheter of FIG. **1** taken along the line **1**A—**1**A;

FIG. **1**B is a cross-sectional view of the catheter with guide wire of FIG. **1** taken along the line **1**B—**1**B;

FIG. **1**C is an enlarged fragmentary perspective view of the encircled catheter section of FIG. **1** at **1**C;

FIGS. **2**A–**2**D are cross-sectional views of the catheter of FIG. **1** located within increasingly larger endoscope channels;

FIG. **3** is a perspective view of an endoscope exchange sheath assembly, without slit, suitable for receiving the catheter of FIG. **1**;

FIG. **3**A is an enlarged fragmentary perspective view of the encircled sheath section of FIG. **3** at **3**A;

FIG. **4** is a perspective view of an alternative embodiment sheath assembly having a slit sheath and two-piece hub, shown in an unlocked position;

FIG. **4**A is a perspective view of the two-piece hub of FIG. **4** in a locked position;

FIG. **4**B is an enlarged fragmentary perspective view of the encircled sheath section of FIG. **4** at **4**B, having a slit;

FIG. **4**C is an enlarged fragmentary perspective view of a sheath section, having an overlap, an alternate embodiment of the sheath in FIG. **4**B;

FIG. **5** is a perspective view of the catheter of FIG. **1** inserted through the endoscope sheath assembly of FIG. **4**;

FIG. **6** is a perspective view of a endoscope sheath section containing a catheter having a U-shaped channel containing a guide wire;

FIG. **7** is a partial perspective view of a guide wire within the catheter of FIG. **1** inserted through the endoscope sheath assembly of FIG. **4**, which is in turn within an endoscope;

FIG. **7**A is a perspective view of the sheath assembly of FIG. **7**, having the catheter removed;

FIG. **8** is a partial perspective view of an alternative embodiment of a sheath assembly, including an introducer;

FIG. **8**A is an enlarged perspective view of the introducer of FIG. **8**;

FIG. **9**A is an enlarged, cross-sectional view of an alternative embodiment of the introducer of FIG. **8**;

FIG. **9**B is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. **8**;

FIG. **9**C is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. **8**;

FIG. **9**D is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. **8**;

FIG. **9**E is an enlarged, perspective view of another alternative embodiment of the introducer of FIG. **8**;

FIG. **9**F is an enlarged, cross-sectional view of another alternative embodiment of the introducer of FIG. **8**;

FIG. **10** is a perspective view of an illustrative locking device;

FIG. **11** is a partial side view of an illustrative locking device positioned on an endoscope having an angled side port;

FIG. **12** is a partial side view detailing the illustrative locking device of FIG. **11**;

FIG. **13** is a perspective view of another illustrative locking device;

FIG. **14** is a perspective view of yet another illustrative locking device; and

FIG. **15** is a partial side view of another illustrative locking device positioned on an endoscope having an angled side port.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** shows a perspective view of a catheter assembly **30** in accordance with the present invention. Catheter assembly **30** is used in catheter procedures for accessing targeted anatomical regions through the alimentary canal. The present invention incorporates features which allow rapid exchange of a catheter by a single operator. The catheter of the present invention allows shorter length guide wires to be used, resulting in procedures which require less medical personnel, are less time consuming, and less costly. Additionally, the present invention is adaptable to most catheter devices used for catheter procedures within the alimentary canal.

Catheter assembly **30** includes a catheter hub assembly **32** and a catheter **34**, having a guide wire **36** passing through a portion thereof. Catheter **34** includes a shaft **38**, which in general terms has a proximal end **40**, a U-channel **42**, a distal tip region **44**, a distal end **46** and various lumens described in greater detail below. Catheter hub assembly **32** is operably connected to proximal end **40** of shaft **38**. Catheter hub assembly **32** is preferably configured to couple to ancillary devices allowing access to a lumen within shaft **38**.

Shaft **38** is a generally tubular shaped member having a generally uniform outer shape at proximal end **40**. Shaft **38** may be sized for slidable passage through the lumen of an endoscope (not shown). Shaft **38** is preferably formed in an extrusion process. Shaft **38** may be formed of an extruded polymeric material. In one embodiment, the preferred polymeric material is polytetrafluoroethylene, polyether block amide, nylon or a combination or blend of these. Catheters which are contemplated include, but are not limited to, cannulas, sphincterotomes, cytology devices, and devices for stone retrieval and stent placement.

In a preferred embodiment, shaft **38** further includes a distal taper **48** which tapers to distal tip region **44**. Additionally, tip region **44** may include high contrast, color coded distal markers **50**. Finally, distal end **46** may be radiopaque for fluoroscopic visualization of distal tip region **44** during a catheter procedure.

U-channel **42** of shaft **38** extends between a first, proximal channel end **52** and a second, distal channel end **54**. U-channel **42** serves to contain, but not necessarily constrain, guide wire **36**, between channel proximal end **52** and channel distal end **54**. The term "U-channel" refers to a channel shape that allows radial removal of guide wire **36** from the channel **42**, and need not be strictly in the shape of the letter U. Channel **42** in the preferred embodiment is sufficiently large to allow unhindered radial guide wire **36** movement out of channel **42**. Further, the channel walls and radial opening are substantially equal to or slightly larger than the diameter of a guide wire lumen, described in greater detail below. Although it is recognized that proximal channel end **52** may be located at any location distal of proximal end **40** of shaft **38**, channel distal end **54** is preferably located between 10 and 40 cm from distal end **46** of catheter shaft **38**.

Finally, as shown in FIG. **1A**, which is a cross-sectional view of shaft **38** taken along line **1A—1A** at a location proximal of channel proximal end **52**, shaft **38** includes ancillary lumen **56**, ancillary lumen **58** and guide wire lumen **60**.

Ancillary lumen **56** and ancillary lumen **58** extend longitudinally between proximal end **40** and distal end **46** of shaft **38**. Ancillary lumen **56** and ancillary lumen **58** may be injection lumens, allowing for high contrast media flow capability for bubble-free opacification and for excellent visualization of a desired anatomical region. Additionally or alternatively, ancillary lumen **56** and/or ancillary lumen **58** may be used for or as part of other ancillary devices, such as a cutting wire lumen or a retrieval balloon lumen.

Guide wire lumen **60** extends longitudinally between proximal end **40** and distal end **46** of shaft **38** in the preferred embodiment. Further, guide wire lumen **60** is sized to receive guide wire **36**. Guide wire lumen **60** may be a tubular member which is extruded integral catheter shaft **38**, or alternatively, guide wire lumen **60** may be a separate tubular member which is coupled to catheter shaft **38**. Although in one preferred embodiment the guide wire lumen **60** is a tubular member which is located proximate distal end **46** of catheter shaft **38**, it is recognized that guide wire lumen **60** may be formed anywhere along shaft **38**, may be an extension of shaft **38** coupled to distal end **46**, or guide wire lumen **60** may run the entire length of shaft **38**.

Referring to FIG. **1B**, a cross-sectional view of shaft **38** taken along line **1B—1B** of FIG. **1** is shown. Guide wire **36** may access guide wire lumen **60** at a point proximal channel distal end **54**. Guide wire **36** extends within channel **42** to channel distal end **54**, continuing within guide wire lumen **60** through distal tip region **44**, and exiting through an opening in distal end **46**.

Referring to FIG. **1C**, a section of catheter shaft **38** having U-channel **42** is shown. The embodiment shown also includes ancillary lumens **56** and **58**. Sections of shaft **38** proximate the channel proximal end **52** and distal channel distal end **54** contain guide wire lumen **60** in communication with U-channel **42**. In one embodiment, U-channel **42** has an interior, closed-side geometry, substantially the same as the geometry of guide wire lumen **60**. Further, U-channel **42** walls are spaced further than a diameter of guide wire **36** such that guide wire **36** moves freely into and out of U-channel **42**.

Catheter shaft **38** can be configured such that U-channel **42** is defined separately from guide wire lumen **60**. With this approach, guide wire lumen **60** is divided into two sections; a first section extending between proximal end **40** of shaft **38** and channel proximal end **52**; and a second portion extending between channel distal end **54** and distal end **46** of shaft **38**. Alternatively, the shaft can be configured to define guide wire lumen **60** as extending longitudinally between proximal end **40** and distal end **46** of shaft **38**. In the alternative embodiment, between channel proximal end **52** and channel distal end **54**, guide wire lumen **60** is integral with U-channel **42**. In other words, guide wire lumen **60** defines a portion of U-channel **42** such that spacing between outer walls of U-channel **42** is equal to a diameter of guide wire lumen **60**. Regardless of how guide wire lumen **60** and U-channel **42** are defined, U-channel **42** provides for access to guide wire lumen **60** at channel distal end **54**. In this regard, channel distal end **54** can be enlarged to more easily direct guide wire **36** into guide wire lumen **60**.

Guide wire lumen **60** and U-channel **42** allow rapid exchange of catheter assembly **30** when an alternative catheter is necessary during a certain medical procedure. Shorter length guide wires may be used since guide wire **36** does not pass through shaft proximal end **40** and hub assembly **32**, but rather exits the catheter shaft **38** at U-channel **42** located substantially distal from proximal end

40. The unique catheter construction in accordance with the present invention will reduce catheter therapeutic and diagnostic procedure time since catheter device exchanges may be performed relatively more easily and quickly by a single operator. Additional personnel and time associated with maintaining the placement of a conventional (approximately 400 cm) guide wire within the targeted anatomical region is eliminated, reducing the overall costs of the procedure.

Referring to FIGS. 2A through 2D, cross-sectional views of endoscope working channels 70–76 containing a catheter according to FIG. 1 are shown. In the examples illustrated in FIGS. 2A through 2D, working channel inside diameters 70, 72, 74, and 76 are 2.8, 3.2, 3.8, and 4.2 mm, respectively. FIG. 2A illustrates catheter shaft 38 having ancillary lumens 54 and 56, U-channel 42, and guide wire 36 within U-channel 42. Further, shaft 38 is shown within a first size endoscope working channel 70. In FIG. 2A, guide wire 36 is effectively radially constrained by small sized working channel 70 that closely surrounds U-channel 42.

FIG. 2B illustrates catheter containment within a second size working channel 72, slightly larger than the working channel 70 of FIG. 2A. In FIG. 2B, guide wire 36 is able to move out of U-channel 42 to a position denoted with dashed lines at 80. FIG. 2C shows shaft 38 contained within a third, even larger sized working channel 74. Guide wire 36 is able to move completely out of U-channel 42 to position 82 shown with dashed lines. Finally, FIG. 2D demonstrates catheter shaft 38 within a fourth size working channel 76. In this even larger working channel, guide wire 36 lies within an even larger cross-sectional area, and is able to move to a position shown in FIG. 2D with dashed lines at 84.

As shown with the larger endoscope working channels (FIGS. 2C and 2D), the potential for guide wire 36 to slip out of U-channel 42 creates a potential for the guide wire 36 to become pinched and restrict desired movements of both guide wire 36 and catheter shaft 38. For this reason, when larger endoscope working channels are used, an exchange sheath having a sufficiently small inner diameter so as to constrain guide wire movement to within the catheter U-channel 42 is employed with the preferred embodiment. Generally speaking, an endoscope exchange sheath in accordance with the preferred embodiment allows for use of a radially accessible guide wire, which is longitudinally aligned with the catheter, while presenting a circular profile to an endoscope and mitigating guide wire pinching problems between the catheter and the endoscope working channel wall.

Referring to FIG. 3, an endoscope exchange sheath assembly 100 having sheath hub assembly 102 and a sheath 104 is shown. The sheath 104 includes a lumen 106 and a distal end 108. FIG. 3A shows a section of sheath 104, having lumen 106 for receiving a catheter. Basically, with reference to FIG. 1, catheter 34 is fed through lumen 106 of sheath 104 such that sheath 104 encompasses guide wire 36 within U-channel 42. Sheath 104 is adapted to be disposed within an endoscope working channel, thereby providing a smaller diameter channel than that of the surrounding endoscope working channel constraining the guide wire 34 (FIG. 1) to the U-channel 50 (FIG. 1), and mitigating the potential problems shown in FIGS. 2C and 2D.

Referring to FIG. 4, an alternate endoscope exchange sheath assembly 110 is shown. Sheath assembly 110 includes a two-piece hub assembly 112 and a sheath 114 defining lumen 116 and having slit 118 extending longitudinally over its length, terminating at distal end 120. Slit 118 in sheath 114 is shown in more detail in FIG. 4B.

Referring again to FIG. 4, two-piece hub assembly 112 has a proximal hub portion 122 and a distal hub portion 124, having a proximal slit 126 and a distal slit 128, respectively. Sheath slit 118 is in communication with hub slits 126 and 128, allowing a guide wire (not shown) to be radially slid into or out of sheath assembly 110. Proximal hub portion 122 is shown unlocked (position "A")in FIG. 4, aligning hub proximal slit 126 with hub distal slit 128 and sheath slit 118, providing a continuous slit for guide wire radial movement into and out of the sheath assembly 110. Proximal hub portion 122 is shown locked, in position "B",in FIG. 4A, whereby proximal hub slit 126 is rotated with respect to distal hub slit 128, preventing a guide wire (not shown) within hub assembly 112 from being moved radially out of hub assembly 112. Proximal hub portion 122 is set to position B (FIG. 4A) when radial guide wire movement is not desired.

FIG. 4C illustrates a portion of an alternate embodiment sheath 130 having a lumen 132, a sheath wall opening 134 and sheath wall overlap 136. A guide wire (not shown) is able to be slid out of lumen 132 of sheath 130 by maneuvering the guide wire into sheath wall opening 134 and through overlap 136.

Referring to FIG. 5, catheter assembly 30 depicted in FIG. 1 is shown inserted within endoscope exchange sheath assembly 110 depicted in FIG. 4. More particularly, catheter 34 is inserted through slitted sheath assembly 110, extending distally out sheath distal end 120. Guide wire 36 (shown partially in FIG. 5) is positioned within U-channel 42 of catheter 34, along guide wire lumen 60 (FIG. 1B), and extends from shaft distal end 46. Further, guide wire 36 is engaged by hub assembly 112. More particularly, guide wire 36 passes within and is engaged by proximal slit 126 and distal slit 128 of hub assembly 112. Sheath proximal hub portion 122, having proximal slit 126, is shown in locked position relative to sheath distal hub portion 124, having distal slit 128. Thus, in the locked position, hub assembly 112 of sheath assembly 110 prevents radial withdrawal of guide wire 36, otherwise inserted in U-channel 42 of catheter 34, from distal the channel proximal end 52.

Referring to FIG. 6, a section of FIG. 5 is shown in detail, having endoscope sheath 114 containing catheter shaft 38, which further maintains guide wire 36 within U-channel 42. As shown, sheath 114 is able to constrain movement of guide wire 36 from U-channel channel 42 when sheath 114 is within a larger endoscope working channel, for example as illustrated in FIGS. 2C and 2D. Importantly, the sheath 114 embodiment illustrated in FIG. 6 includes longitudinal slit 118, allowing guide wire 36 to be peeled from catheter shaft 38 and endoscope sheath 114. In other words, as previously described, U-channel 42 is sized larger than guide wire 36 such that guide wire 36 can displace radially from U-channel 42. Sheath 114 prevents undesired displacement of guide wire 36 from U-channel channel 42 under normal operating conditions. However, if adequate radial force is placed on guide wire 36 by an operator, guide wire 36 will separate sheath 114 along slit 118 such that guide wire 36 is displaced from sheath 114 and U-channel 42. Referring to FIG. 7, guide wire 36 is shown inserted within catheter assembly 30 of FIG. 1, which is inserted through endoscope sheath assembly 110 of FIG. 4, which is in turn within an endoscope 150. Sheath assembly 110 includes sheath 114 that has slit 118 and two-piece hub assembly 112, shown at a locked position "B" (also in FIG. 4A). Having hub assembly 112 locked prevents guide wire 36 from moving radially out of sheath 114 through slit 118. Guide wire 36 can be restrained from longitudinal movement by applying finger pressure on the guide wire 36 against hub assembly 112.

Referring to FIG. **7**A, endoscope **150** and sheath assembly **110** of FIG. **7** are shown without the catheter assembly **30** inserted, as after catheter withdrawal. Sheath hub assembly **112** is shown in unlocked position at "A" (also in FIG. **4**). Having hub assembly **112** unlocked allows radial movement of guide wire **36** out of sheath **114** through slit **118**, but such movement may be restrained by trapping guide wire **36** against the outside of sheath **114** using one finger, providing ease of guide wire **36** control during catheter exchanges.

In one possible endoscopic procedure, an endoscope **150**, as illustrated in FIG. **7**, is first introduced into the mouth of a patient and is guided through the patient's alimentary canal. Specifically, endoscope **150** is guided down the esophagus, through the stomach, past the pyloric sphincter of the stomach and into the duodenum. Endoscope **150** has a lumen extending longitudinally between its proximal end and the distal end. Endoscope **150** is guided through the alimentary canal until a distal end (not shown) of endoscope **150** is proximate the target area within the anatomy to receive treatment. In an endoscopic biliary procedure, endoscope **150** is guided into the duodenum until the opening at the distal end of the endoscope **150** is proximate the papilla of vater. The papilla of vater is located between the sphincter of oddi, which leads to the common bile duct, hepatic, and pancreatic ducts. The proximal end (shown in FIGS. **7** and **7**A) of endoscope **150** extends and remains outside the mouth of the patient.

With endoscope **150** properly positioned within the patient, catheter assembly **30** is prepared for insertion into the endoscope. First, guide wire **36** is fed into the guide wire lumen **60** (FIGS. **1**A–**1**C) of shaft **38**. More particularly, a distal end of guide wire **36** is placed within U-channel **42**, distal the channel proximal end **52**. The guide wire **36** is then fed to channel distal end **54** (FIG. **1**) into guide wire lumen **60**. Finally, guide wire **36** is fed through shaft **38** to distal tip region **40** (FIG. **1**). In one method, catheter **32** is then inserted directly into endoscope **150** working channel. This method may be practiced with an endoscope having a sufficiently small working channel inside diameter, as illustrated in FIG. **2**A, to constrain guide wire **36** movement without a sheath.

However, in a preferred method (with reference to FIG. **7**), catheter assembly **30**, threaded with guide wire **36**, is inserted into sheath assembly **110**, thereby constraining guide wire **36** from slipping radially out of U-channel **42**. More particularly, catheter **34** is inserted into endoscope **150** working channel, but leaving channel proximal end **52** proximate sheath hub assembly **112**, and leaving a portion of guide wire **36** extending from the channel proximal end **52** as well. Notably, sheath hub assembly **112** includes hub slits **126** and **128** which receive a portion of guide wire **36**. Thus, in the preferred embodiment, hub assembly **112** is locked, preventing unwanted radial guide wire **36** movement. In a preferred method, the loading of guide wire **34** into catheter shaft **38** and catheter shaft **38** into sheath assembly **110** is done prior to inserting endoscope **150** into a patient (not shown).

Endoscope sheath **114**, containing catheter shaft **38**, is inserted into endoscope **150** working channel. Endoscope sheath **114** serves to constrain radial guide wire **36** movement over the approximate length of U-channel **42**. Catheter shaft **38** and sheath **114** are inserted together into endoscope **150** until both are near a distal end (not shown) of endoscope **150**. Catheter shaft **38** and sheath **114** may be, either or both, advanced until exiting the distal end of endoscope **150**.

In one method, guide wire **36** is advanced until guide wire **36** distal tip is positioned within the target area in the biliary tree (including the common bile, hepatic or pancreatic ducts). For example, the distal tip of guide wire **36** may be guided through the orifice leading to the papilla of vater for access to the biliary tree. Catheter shaft **38** may then be advanced over guide wire **36**, tracking catheter assembly **30**, until catheter distal tip region **40** (FIG. **1**) exits distal end of endoscope **150** and is positioned within the desired duct. In another method, guide wire **36** and catheter assembly **30** are advanced together until catheter distal end **42** (FIG. **1**) is positioned at the target area. It is also recognized that the catheter could be first advanced to near the target area, followed by inserting the guide wire when needed to advance the catheter further.

Once guide wire **36** is in position at the target area, catheter procedures, including injecting contrast media, such as radiopaque dye, through ancillary lumens **56** or **58** (FIGS. **1**A–**1**C) into the common bile duct for visualization of the duct, can be performed. After the desired catheter procedure has been completed, catheter assembly **30** can be exchanged or removed from endoscope **150**, leaving guide wire **36** in position for other catheter procedures. Catheter assembly **30** and sheath assembly **110** may also be removed together.

One method of withdrawing catheter **34** from endoscope **150** is possible using either a slitted/overlapped endoscope sheath **114** as depicted in FIGS. **4** through **4**C, or a sheath **104** without a slit as depicted in FIGS. **3** through **3**A. Using this method, best visualized with reference to FIG. **7**, guide wire **36** is held to prevent longitudinal movement while catheter **34** is retracted within endoscope sheath **114** (or **104**). Catheter **34** retraction leaving the guide wire **36** in position within the patient is enabled by U-channel channel **42** being radially open to guide wire **36** removal in catheter shaft **36**. Once catheter retraction has brought channel distal end **54** (FIG. **1**) to a point proximate sheath hub assembly **112**, only a relatively short portion of guide wire **36**, from channel distal end **54** to distal end **46** (FIG. **1**) of catheter shaft **38**, remains within catheter **34**. A single operator can remove this remaining portion of guide wire **36** from catheter **34** by first slightly retracting catheter assembly **30** (while still holding guide wire **34** in place) out of sheath assembly **110** (or **100**), such that a portion of guide wire **36** is accessible distal of catheter distal end **46**. In other words, a small portion of guide wire **36** is accessible between distal end **46** of catheter **34** and distal hub portion **124** of sheath assembly **110**. The accessible portion of guide wire **36** is then held by the operator, while withdrawing the remaining portion of catheter **34** completely over guide wire **36**. In an alternative method, the distal end of the endoscope can include an elevator which could be utilized to lock the distal end of the guide wire in position while the catheter is removed.

Exchange of endoscope sheath assembly **110** may be desired, as when a stent (not shown) is to be advanced over guide wire **36**, and the stent has a larger outside diameter than can be accommodated by the sheath **114**. One method of exchanging an endoscope sheath assembly **110** may be used where sheath **114** is slitted as in FIG. **4**B, or overlapped, as in sheath **130** in FIG. **4**C. Referring to FIG. **7**A, two-piece hub assembly **112** is turned to the unlocked position "A" (also shown in FIG. **4**). Guide wire **36** is pulled radially away from sheath hub assembly **112** and through slit **118** in sheath **114**. Guide wire **36** is then held, preferably against some portion of endoscope **150**, to prevent guide wire **36** from being dislodged from position within the patient. Sheath **114** is retracted from endoscope **150**, guide wire **36** being "peeled" away from sheath **114**. Sheath retraction is continued until sheath **114** is completely outside of endo-

scope **150** and over guide wire **36**. At this point, guide wire **36** is within endoscope **150** working channel, and stents, catheters, and endoscope sheaths may be advanced over guide wire **36**.

Another method of exchanging both endoscope sheath assembly **110** and catheter assembly **30** may be used where the sheath **114** is slitted as in FIG. **4**B, or overlapped, as in sheath **130** in FIG. **4**C. Referring to FIGS. **7** and **7**A, two-piece hub assembly **112** is turned to the unlocked position "A" (FIG. **7**A). Guide wire **36** is pulled radially away from U-channel **42** of catheter **34**, from hub assembly **112** and through slit **118** in sheath **114**. Guide wire **36** is then held, preferably against some portion of endoscope **150**, to prevent guide wire **36** from being dislodged from position within the patient. Sheath **114** and catheter **34** are retracted from endoscope **150**, with guide wire **36** being "peeled-"away from sheath **114**. Sheath assembly **110** and catheter assembly **30** retraction are continued until sheath **114** and catheter **34** are completely outside of endoscope **150** and over guide wire **36**. At this point, guide wire **36** remains in a position within endoscope **150** and patient. A single operator can access a small portion of guide wire **36** between distal end **46** (FIG. **1**) of catheter **34** to hold guide wire **36** in place while catheter assembly **30** is completely removed or disengaged from guide wire **36**.

While sheath assembly **110** has been described as including a two-piece hub assembly **112** in conjunction with sheath **114**, other assemblies may be used. For example, referring to FIG. **8**, an alternate sheath assembly **160** is shown. Sheath assembly **160** includes an introducer **162**, an attachment means **164** and a sheath **166**. Similar to previous embodiments, sheath **166** defines a lumen (not shown) and includes a slit **168** extending longitudinally over its length, terminating at a distal end **170**. Sheath **166** is generally identical to sheath **104** and sheath **114** previously described. Introducer **162** is attached to sheath **166** by attachment means **164** such that lumen (not shown) of sheath **166** is in fluid communication with an interior portion of introducer **162**. In one preferred embodiment, attachment means **164** is a flexible membrane which seals sheath **166** to introducer **162**. Alternatively, other forms of attachment, such as an adhesive or frictional engagement between introducer **162** and sheath **166** may also be useful.

Referring to FIG. **8**A, introducer **162** is shown in greater detail. Introducer **162** is a funnel-shaped device including a horn **172** and a neck **174**. In one preferred embodiment, horn **172** and neck **174** are integrally formed as a singular body.

Horn **172** is preferably a conically-shaped body having an outer wall **176**. Outer wall **176** defines an interior space and includes a guide wire-receiving notch **180** formed near proximal end **182** of horn **172**. Guide wire-receiving notch **180** is preferably J-shaped shaped and includes an entry end **184** and a locking end **186**. As shown in FIG. **8**A, entry end **184** is open at proximal end **182** of horn **172**. Conversely, locking end **186** is closed.

Neck **174** is preferably tubular in shape, and includes a passage **188**. Passage **188** is configured to be in fluid communication with interior space of horn **172**. In the preferred embodiment, horn **172** and neck **174** are formed of a plastic material. Alternatively, any other semi-rigid or rigid, surgically-safe material may be used.

Referring to FIGS. **1**, **8** and **8**A, during use, catheter assembly **34** (FIG. **1**) is inserted within sheath assembly **160**. More particularly, distal end **46** (FIG. **1**) of catheter shaft **38** (FIG. **1**), including guide wire **36** (FIG. **1**) is placed within horn **172** of introducer **162**. The conical shape of horn **172** assists in directing distal end **46** of catheter shaft **38**, including guide wire **36**, into passage **188** of neck **174**. Catheter shaft **38** continues forward within lumen (not shown) of sheath **166** until distal end **46** of catheter shaft **38** extends from distal end **170** of sheath **166**.

Once properly inserted within sheath assembly **160**, a proximal end of guide wire **36** (FIG. **1**) is maintained within guide wire-receiving notch **180**. More particularly, a portion of guide wire **36** is forced by an operator through entry end **184** of guide wire-receiving notch **180** and forced within locking end **186** thereof In this regard, locking end **186** preferably has a diameter slightly smaller than that of guide wire **36**. Thus, locking end **186** frictionally maintains guide wire **36**. Conversely, guide wire **36** can easily be released from guide wire-receiving notch **180** by sliding guide wire **36** from locking end **186** and out of entry end **184**. Thus, sheath assembly **160** functions in a manner highly similar to sheath assembly **100** and sheath assembly **110** previously described.

Referring to FIG. **9**A, an alternative embodiment of an introducer **190** is shown. Introducer **190** includes a horn **192**, a neck **194** and a valve **196**. Similar to previous embodiment, horn **192** and neck **194** are preferably integrally formed as a singular body. Horn **192** includes an outer wall **197** which defines a guide wire-receiving notch **198** and valve-receiving slots **200**. Valve **196** includes a valve body **202** sized to fit within outer wall **197** of horn **192**. Further, valve **196** includes ribs **204** extending from valve body **202**. Ribs **204** are preferably sized to mate within valve-receiving slots **200** of horn **192**. Thus, valve **196** is maintained within horn **192** via interaction of ribs **204** with valve-receiving slots **200**. In this regard, valve-receiving slots **200** are preferably positioned along horn **192** proximal neck **194**. Valve **196** is preferably made of a rubber-type material.

During use, introducer **190** functions in a manner highly similar to introducer **162** (FIGS. **8** and **8**A) previously described. Additionally, however, valve **196** forms a seal about catheter shaft **38** (FIG. **1**). Thus, upon insertion into a human body, valve **196** prevents bodily fluids, such as bile, from backing up through the sheath assembly. Additionally, valve **196** can provide for aspiration, if desired.

Referring to FIG. **9**B, an alternative embodiment of an introducer **206** is shown. Introducer **206** is highly similar to introducer **190** (FIG. **9**A) previously described. In this regard, introducer **206** includes a horn **208**, a neck **210** and a valve **212**. Horn **208** is preferably integrally formed with neck **210** and includes an outer wall **214** defining a guide wire-receiving notch **216** and valve-receiving slots **218**. Similar to valve **196** (FIG. **9**A), valve **212** includes a valve body **220** and ribs **222**. Ribs **222** are sized to mate within valve-receiving slots **218** of horn **208**. In this regard, valve-receiving slots **218** are positioned proximate a proximal end **224** of horn **208**. Introducer **206**, including valve **212**, functions in a manner highly similar to introducer **190** (FIG. **9**A) as previously described.

It is recognized that the fluid blocking function provided by valve **212** can be achieved with other designs. For example, referring to FIG. **9**C, an alternative embodiment of an introducer **226** is shown. Introducer **226** includes a horn **228**, a neck **230** and an O-ring **232**. Horn **228** and neck **230** are preferably formed as an integral body. Horn **228** preferably includes a guide wire-receiving notch (not shown) similar to that previously described and an interior slot **234**. Interior slot **234** is preferably positioned proximate neck **230** and is sized to maintain O-ring **232**. Alternatively, interior slot **234** can be formed in neck **230**.

O-ring **232** is preferably made of a rubber-type material. Further, O-ring **232** has an inner diameter slightly smaller than that of horn **228** and neck **230**. Thus, during use, O-ring **232** forms a seal about catheter shaft **38** (FIG. **1**), blocking passage of bodily fluids, such as bile, into horn **228**.

Referring to FIG. **9**D, another alternative embodiment of an introducer **236** is shown. Introducer **236** is similar to a touhey-borst system and includes an upper horn section **238**, a lower horn section **240** and a grommet **242**. Upper horn section **238** includes an outer wall **244** defining a proximal end **246**, a grommet-receiving flange **248** and a distal end **250**. Proximal end **246** of horn section **238** preferably includes a guide wire-receiving notch (not shown) similar to that previously described. Distal end **250** is threaded and includes a passage **252** sized to receive a portion of lower horn section **240**.

Lower horn section **240** includes a body **254** defining a proximal end **256**, an intermediate portion **258** and a distal end **260**. An interior passage **266** is configured to communicate with passage **252** and extends from proximal end **256** to distal end **260**. Finally, proximal end **256** includes a threaded slot **262** sized to threadably receive distal end **250** of upper horn section **238**.

Grommet **242** is preferably made of a rubber-type material and is sized to nest within grommet-receiving flange **248** of upper horn section **238** while abutting proximal end **256** of lower horn section **240**.

Introducer **236** is assembled by placing grommet **242** within grommet-receiving flange **248** of upper horn section **238**. Distal end **250** of upper horn section **238** is then threadably secured to proximal end **258** of lower horn section **240**. As upper horn section **238** is threadably secured to lower horn section **240**, proximal end **256** of lower horn section **240** compresses grommet **242** within grommet-receiving flange **248** of upper horn section **238**. During use, introducer **236** functions in a manner highly similar to that previously described. In this regard, grommet **242** forms a seal about catheter shaft **38** (FIG. **1**). Further, aspiration can be achieved, if desired, by loosening lower horn section **240** relative to upper horn section **238**.

Referring to FIG. **9**E, yet another alternative embodiment of an introducer **266** is shown. Introducer **266** includes a horn **268**, a neck **270** and a valve **272**. Preferably, horn **268**, neck **270** and valve **272** are integrally formed as a singular body. In this regard, valve **272** is formed while molding horn **268** and neck **270** by imparting a controlled flash at distal end **274** of neck **270**.

Introducer **266** performs in a manner highly similar to that previously described. Thus, valve **272** forms a seal about catheter shaft **38** (FIG. **1**), thereby preventing back flow of bodily fluids, such as bile, into horn **268**.

Referring to FIG. **9**F, another alternative embodiment of an introducer **276** is shown. Introducer **276** includes a horn **278**, a neck **280** and a valve **282**. Horn **278** and neck **280** are preferably integrally formed as a singular body. In this regard, horn **278** and neck **280** are defined by an outer wall **284**. Outer wall **284** forms a guide wire-receiving notch **286** and an exterior slot **288**. Guide wire-receiving notch **286** is similar to that previously described. Exterior slot **288** is positioned along neck **280** and is sized to maintain a portion of valve **282**. Alternatively, exterior slot **288** can be positioned along horn **278**.

Valve **282** is preferably a rubber-type sock defined by an upper rib **290**, a side wall **292** and a shoulder **294**. Upper rib **290** is preferably sized to mount within exterior slot **288** of neck **280**. Side wall **292** is preferably flexible so as to stretch along neck **280**. Finally, shoulder **294** is preferably configured to abut a distal end **298** of neck **280**. With this configuration, valve **282** is placed over distal end **298** of neck **280** such that shoulder **294** contacts distal end **298**. Due to the preferred flexible characteristic of valve **282**, side wall **292** is stretched until upper rib **290** nests within exterior slot **288** of neck **280**.

During use, the catheter shaft **38** (FIG. **1**) is placed through introducer **276** such that shoulder **294** of valve **282** forms a seal about catheter shaft **38**. Thus, valve **282** prevents undesired back flow of bodily fluids, such as bile.

FIG. **10** is a perspective view of an illustrative locking device for use with an endoscope having a side instrument port. The illustrative locking device is generally shown at **320** and includes a body member **322**. At one end, the body member **322** includes one or more hook members **324** for attaching the locking device to a shaft of an endoscope or the like (see FIG. **11**). At the other end, the body member **322** includes a securing mechanism for securing a guide wire or catheter to the locking device.

The hook members **324** may be provided in pairs, as shown in FIG. **10**, or offset from one another, as shown in FIG. **13**. In either case, the hook members **324** are adapted to clip and secure the locking device to the shaft of an endoscope or the like.

The securing mechanism preferably includes one or more openings provided in the body member **322**. In the embodiment shown, the body member **322** includes a guide wire opening **326** and a catheter opening **332**. The guide wire opening **326** is similar to the guide wire-receiving notch **180** of FIG. **8**A. The guide wire opening **326** is preferably J-shaped, and preferably includes an entry slot **328** and a locking slot **330**. The catheter opening **332** is boot shaped, and also preferably includes an entry slot **334** and a locking slot **336**.

The entry slot **328** of the guide wire opening **326** is dimensioned to be larger than the diameter of a guide wire. The locking slot **330** of the guide wire opening **326** is dimensioned to be somewhat smaller than the diameter of a guide wire. Accordingly, a guide wire can be secured to the body member **322** by inserting a portion of the guide wire through the entry slot **328** of the guide wire opening **326** and into the locking slot **330**. The locking slot **330** frictionally secures the guide wire relative to the body member **322**.

Likewise, the entry slot **334** of the catheter opening **332** is dimensioned to be larger than the diameter of a catheter. The locking slot **336** of the catheter opening **332** is dimensioned to be somewhat smaller than the diameter of a catheter. Accordingly, a catheter can be secured to the body member **322** by inserting a portion of the catheter through the entry end **334** of the catheter opening **332** and into the locking slot **336**. The locking slot **336** frictionally secures the catheter relative to the body member **322**.

FIG. **11** is a partial side view of an illustrative locking device positioned on an endoscope with an angled side port extending therefrom. The endoscope is generally shown at **350**, and includes a main shaft **352** with a lumen extending therethrough. A side port **356** extends laterally away from the main shaft **352** at an angle. The side port **356** provides access to the lumen of the main shaft **352**. Accordingly, a guide wire and/or catheter may access the lumen of the main shaft **352** via the side port **356**.

The side port **356** preferably includes a side port opening **354** which is laterally spaced from the main shaft **352** due to the angular displacement between the main shaft **352** and the side port **356**. The side port opening **354** is in fluid com-

munication with the lumen of the main shaft **352** via a connection tube **355**. The connection tube **355** intersects a side wall of the main shaft **352** at an angle, as shown.

A locking device having a body member **360** is shown clipped onto the main shaft **352** of the endoscope. The body member **360** includes a number of hook members **358** for attaching the locking device to the main shaft **352**. Two hook members are visible in FIG. **11**. The hook members **358** are similar to the hook members **324** described above with respect to FIG. **10**.

The body member **360** extends away from the hook members **358** and generally parallel to the side port **356**. In FIG. **11**, the body member is obscured by the main shaft **352** and side port **356**. The body member **360** extends upward past the side port opening **354**, wherein a securing mechanism is provided. Preferably, the securing mechanism is a j-shaped guide wire opening **362**.

In use, a guide wire is advanced into the body via the endoscope. During the advancement of the guide wire, the proximal end thereof may be moved to a first position **364**, which is in the entry slot of the guide wire opening **362**. Once the guide wire is in a desired position within the body, the guide wire may be moved to a second position **366**, which is in the locking slot of the guide wire opening **362**. The locking slot of the guide wire opening **362** frictionally secures the guide wire relative to the body member **360**.

FIG. **12** is a partial side view detailing the illustrative locking device of FIG. **11**, with an additional oversized catheter opening shown. The side port of the endoscope is shown at **356**, and the body member of the locking device is shown at **360**. Positioned proximate the side port opening **354** is a guide wire opening **362** and an oversized catheter opening **370**. Like above, the guide wire opening is J-shaped and includes an entry slot and a locking slot. Thus, the guide wire may be moved to the first position **364**, which is in the entry slot of the guide wire opening **362**. Once the guide wire is in a desired position within the body, the guide wire may be moved to the second position **366**, which is in the locking slot of the guide wire opening **362**. The locking slot of the guide wire opening **362** frictionally secures the guide wire relative to the body member **360**.

The oversized catheter opening **370** is sized to restrict lateral movement of the catheter **372** but not longitudinal movement of the catheter **372**. Providing a guide wire opening that can secure the guide wire relative to the body member, and an oversized catheter opening for only restricting lateral movement of the catheter **372** may be particularly useful in performing a catheter exchange procedure. For example, during a catheter exchange procedure, the guide wire opening may maintain the position of the guide wire. The oversized catheter opening **370** may separate the catheter from the guide wire, as the catheter is withdrawn. The first and second catheters should be single-operator exchange type catheters to provide access to the guide wire during the exchange.

FIG. **13** is a perspective view of another illustrative locking device. The embodiment shown in FIG. **13** is similar to the embodiment shown in FIG. **10**, but the hook members are laterally offset rather than aligned. For example, hook member **380** is laterally offset from hook member **382** by a distance "D".This configuration is another example of an attachment mechanism for attaching the body member to a catheter shaft.

FIG. **14** is a perspective view of yet another illustrative locking device. The locking device is generally shown at **400**, and includes a body member **401** having an attachment mechanism **402** at one end and a securing mechanism **404** at the other. The attachment mechanism **402** includes a first hook member **406** and a second hook member **408**. The first hook member **406** and the second hook member **408** are adapted to extend around a substantial portion of the shaft of an endoscope or the like. Thus, the first hook member **406** and the second hook member **408** may clip the body member **401** to the desired shaft.

The securing mechanism **404** includes a J-shaped guide wire opening **410** and a flap-type catheter opening **412**. The J-shaped guide wire opening **410** operates similar to that described above. The flap-type catheter opening **412** has a flap **414** formed by cutting the catheter opening **412** from the body member **401**. The flap **414** is preferably curved to form a channel **416**, wherein the end portion **418** of the channel **416** loops back to near the surface of the body member **401**. In this configuration, a catheter or guide wire may be selectively provided in the channel **416**, which may bend the flap away from the body member **401**. Accordingly, the flap **412** may provide force between the guide wire or catheter and the body member **401** to effectively secured the guide wire or catheter to the body member **401**.

FIG. **15** is a partial side view of yet another illustrative locking device **500**. The locking device **500** is positioned between the side port **504** and the main shaft **506** of the endoscope **502**. The locking device includes a body member **510** that is attached to the main shaft **506** using a strap **512**. Preferably, the strap **512** extends around the entire circumference of the main shaft **506**. Further, the body member **510** may include a guide wire opening **514** and one or more catheter openings **516**, as shown. It will be understood that this disclosure, in many respects, is only illustrative. Changes may be made in details, particularly in matters of shape, size, material, and arrangement of parts without exceeding the scope of the invention. Accordingly, the scope of the invention is as defined in the language of the appended claims.

What is claimed is:

1. A medical system comprising:

an endoscope;

an elongate medical device adapted to be inserted into the endoscope; and

a locking device attached to the endoscope having a locking portion and secured to the elongate medical device to limit relative axial movement between the endoscope and the elongate medical device when the elongate medical device is received in the locking portion and to allow relative axial movement between the endoscope and the elongate medical device when the elongate medical device is out of the locking portion;

wherein the elongate medical device comprises at least one of a catheter and a guide wire.

2. A medical system as in claim **1**, wherein the locking device is releasably secured to the elongate medical device.

3. A medical system as in claim **1**, wherein the endoscope includes a proximal port and wherein the locking device is attached to the endoscope distal of the proximal port.

4. A medical system as in claim **3**, wherein the locking device is secured to the elongate medical device proximal of the proximal port.

5. A medical system as in claim 4, wherein the elongate medical device comprises a catheter.

6. A medical system as in claim 4, wherein the elongate medical device comprises a guidewire.

7. A medical system as in claim 1, wherein the locking device comprises a body member having a proximal portion and a distal potion, a means for attaching the body member to the endoscope, the attaching means connected to the distal portion of the body member, and a means for securing the elongate medical device, the securing means connected to the proximal portion of the body member.

8. The medical system of claim 1, wherein the locking device is releasably attached to the endoscope.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,663,597 B1
DATED : December 16, 2003
INVENTOR(S) : Jim Windheuser et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

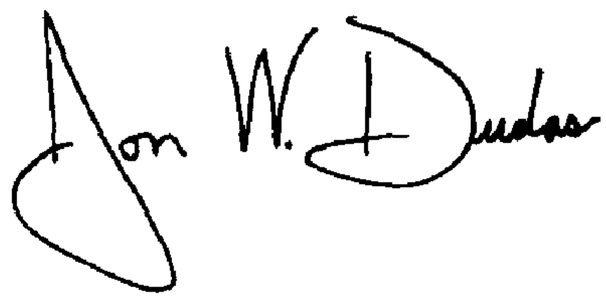
Column 8,
Line 43, delete "U-channel channel 42", and insert therefor -- U-channel 42 --.

Column 10,
Line 31, delete "U-channel channel", and insert therefor -- U-channel --.

Column 11,
Line 52, delete "J-shaped shaped", and insert therefor -- J-shaped --.

Signed and Sealed this

Sixth Day of July, 2004



JON W. DUDAS
Acting Director of the United States Patent and Trademark Office